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ACCESS TO MEDICINES AND INTELLECTUAL PROPERTY: THE CONTRIBUTION OF THE WORLD HEALTH ORGANIZATION

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ABBREVIATIONS AND ACRONYMS

AIDS	Acquired Immunodeficiency Syndrome
BITs	Bilateral Investment Treaties
CEWG	Consultative Expert Working Group on Research and Development: financing and coordination
CIPIH	Commission on Intellectual Property Rights, Innovation and Public Health
DAP	Drugs Action Programme
EU	European Union
EWG	Expert Working Group on R&D financing and coordination
FTAs	Free Trade Agreement
GSPOA	Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property
HIV	Human Immunodeficiency Virus
IP	Intellectual property
MPP	Medicines Patent Pool
NGO	Non-Governmental Organization
PAHO	Pan American Health Organization
PhRMA	Pharmaceutical Research and Manufacturers of America
R&D	Research and Development
SEARO	World Health Organization South East Asia Regional Office
TRIPS	The Agreement on Trade Related Aspects of Intellectual Property Rights
UN	United Nations
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNASUR	Union of South American Nations
UNCTAD	United Nations Conference on Trade and Development
UNDP	United Nations Development Programme
UNICEF	United Nations Children's Fund
US	United States of America
WHA	World Health Assembly
WHO	World Health Organization
WHO/EB	Executive Board of the World Health Organization
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

I. INTRODUCTION

The topic of intellectual property first appeared in the WHO in 1996 and coincided with the end of the Uruguay Round and the creation of the World Trade Organization. In 1995 the Charles III University of Madrid with the WHO Drugs Action Programme (DAP) organized a conference where Professor Carlos Correa[3] presented a paper entitled "The Uruguay Round and Drugs"[4]. The 40 page article analyzes the possible implications of the WTO Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS) on access to medicines and discloses the "room to manoeuvre" that the Agreement has to protect Public Health. This article, "The Uruguay Round and Drugs", was the first document that specifically alerted the health sector of the possible implications of the TRIPS Agreement on public health and in particular, on access to medicines.

Even during negotiations of the Uruguay Round (1986-1994) some negotiators from developing countries foresaw that the TRIPS Agreement would have important implications in relation to pharmaceuticals and health. Shortly after its adoption, the United Nations Conference on Trade and Development (UNCTAD) published a study on the TRIPS Agreement and developing countries[5].

II. FIRST MANDATE OF THE WORLD HEALTH ASSEMBLY

In the World Health Assembly in 1996, a resolution on drugs was adopted[6] that constituted the first mandate given by member states to the secretariat of the WHO to work on intellectual property in relation to health. Originally it was a classic draft resolution dealing with all the components of a drug policy; selection, rational use, quality control, etc., until the last minute, before its adoption by the World Health Assembly, when the delegate of Iran requested an amendment that involved asking the Director General of the WHO to conduct a study on what the impact of the rules of the World Trade Organization, especially the TRIPS Agreement, would be on national drug policies and essential drugs. The 49th World Health Assembly subsequently unanimously adopted the resolution (Resolution 49.14) which incorporated the amendment proposed by Iran.

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[3] Negotiator of the TRIPS Agreement during the Uruguay Round, as Under-Secretary for Science and Technology of the Government of Argentina.

[4] Carlos M. Correa, "The Uruguay Round and drugs", WHO/TFHE/97.1, Distr: General, Original: English, 1997, p. 40.

[5] 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).

[6] WHA 49.14 "Revised Drug Strategy", WHO, Geneva, 1996.

III. "THE RED BOOK"[7]

The request in resolution 49.14 of 1996 for the Director General to prepare a study on the implications of the TRIPS Agreement, was entrusted to the Drugs Action Programme -DAP- which published a document: "Globalization and Access to Drugs: Implications of the WTO/TRIPS Agreement" [8] in November 1997.

The executive summary of the document clearly expresses its objective: "The aim of this document is to inform people in the health sector with no particular legal background about the impact of globalization on access to drugs, and especially about the WTO agreement on intellectual property (TRIPS Agreement) that may have repercussions in the pharmaceutical field". And later in the executive summary the document affirms that "the TRIPS standards derive from those of industrialized countries and are not necessarily appropriate for all countries' level of development. Public health concerns should therefore be considered when implementing the Agreement."[9]

The document, published by the WHO, provoked a series of violent criticisms by the Pharmaceutical Research and Manufacturers of America – PhRMA. According to a letter from PhRMA dated June 30, 1998, the document published by the WHO is "a deeply flawed document that misleads its readers and creates a false impression of how the WTO's TRIPS agreement will affect pharmaceuticals. The paper seeks to rationalize the continued piracy of pharmaceuticals inventions (…) and encourage WHO members not to implement adequate and effective intellectual property protection for pharmaceuticals".[10] The letter from PhRMA was followed by a letter from the Government of the United States dated 28 July 1998[11] accusing the document of "attacking" the WTO TRIPS Agreement and, more than "inform", it spreads "propaganda" against the Agreement.[12] In light of these attacks, the Director General of the WHO, G.H. Brundtland, decided to send the document to be revised by three independent academics specialized in intellectual property from the University of Louvain, Belgium; University of Buenos Aires, Argentina and the Vanderbilt Law School, USA. The experts concluded that the WHO's document is technically correct and fully consistent with the TRIPS Agreement.[13]

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[7] "This (WHO) monograph, nicknamed the Red book", see Velásquez, G. Correa, C., Balasubramaniam, T., "WHO in the frontlines of the access to medicines battle: The debate on Intellectual property rights and public health", in *Intellectual Property in the context of the WTO TRIPS Agreement: Challenges for public health*, edited by Bermudez, J.,(FIOCRUZ, ENSP, WHO, PAHO, Rio de Janeiro, 2004), p. 87.

[8] Velásquez, G., Boulet P., "Globalization and Access to Drugs: Implications of the WTO/TRIPS Agreement", WHO/DAP/98.9, Geneva, November 1997, 58 pg.

[9] Ibid, p. 3 and 4.

[10] Benkimoun P. "Morts sans ordonnance" Ed. Hachette Literatures, Paris, 2002, p. 185

[11] Benkimoun P. op.cit. p. 185 Letter from the Government of the United States of America, signed by the Commissioner of Health Affairs of the FDA, Stuart Nightingale.

[12] The secretariat of the WTO provided a series of commentaries mostly regarding editorial and translation issues and some dissident opinions that the WHO decided to maintain, but the message and the objective of the document was not changed in any way. The original WHO document was in French and the WTO analyzed the English version.

[13] Benkimoun P. op.cit p. 187, 188

The WHO document was printed, by chance, with a red cover and was referred to as the "red book" even in official correspondence. Subsequently, in its first re-print, it became the "blue book".[14]

In 1996 DAP began what F. Antezana and X. Seuba called the fourth phase of the WHO drugs action program: "Economic, Technological and Social Determinants of Health and New Tools"[15].

The economic dimension of drugs was always linked to DAP, a relationship that was deepened from the beginning of the 1990s in the publications and advice given to countries. The publication of the "red book" on "Globalization and Access to Drugs: Implications of the WTO/TRIPS Agreement" "anticipated what the Doha Declaration later came to recognize: the right of WTO members to fully exploit the flexibilities contained in the Agreement in order to protect public health".[16]

Between 1997 and 1999, pursuant to World Health Assembly resolutions[17], DAP carried out a series of activities involving pharmaceuticals and trade. Among the activities was the analysis and dissemination of information regarding the effect of trade agreements on health, advising States to guarantee access to medicines under such agreements, and participation in international conferences on the relation between trade and public health.

In 1999, Director General G.H. Brundtland stated that "when trade agreements affect health, the WHO should be involved from the very beginning",[18] therefore the WHO and DAP in particular, began to analyze existing agreements as well as trade agreements under negotiation in relation to their effects on access to drugs. After considering the Revised Drug Strategy, in 1999 the World Health Assembly encouraged the continuation and expansion of work undertaken, especially regarding the impact of trade agreements on access to patented drugs.[19]

The work of DAP and the WHO was not limited to the analysis of trade agreements but it also extended to the resolution of problems caused by certain interpretations of these agreements. For example, at the end of the 1990s the WHO came out in support of South Africa following a lawsuit by 39 pharmaceutical companies against the South African government's attempt to make use of TRIPS flexibilities. In fact, DAP collaborated with the national South African drug programme, which was considered particularly important because of its possible impact on other countries, performing activities such as advising on drug legislation and the creation of an essential medicine list.

During the second half of the 1990s, DAP incorporated human rights into the work of the WHO regarding access to drugs as a part of the right to health. In the year 2000, the Committee on Economic, Social and Cultural Rights stated that access to essential medicines

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[14] The cover of the first edition of the WHO document was red, the same color as the first edition of the TRIPS Agreement. Apparently this was not appreciated by some individuals who requested that the color of the cover of the WHO document be changed, so today the cover is blue.

[15] Antezana, F. and Seuba, X., Thirty Years of Essential Medicines, The challenge. Ed. Icaria, Milenrama, Barcelona, 2008, p. 42.

[16] Op. cit., p. 44.

[17] 1996 WHA49.14: Revised drug strategy, 1999 WHA52.19: Revised drug strategy.

[18] "WHO gets the mandate to tackle trade impacts on health", Essential Drugs Monitor. No.27, 1999, p.18.

[19] WHA52.19: Revised drug strategy

is a vital element of the right to health,[20] which was supported by a series of resolutions of the United Nations Sub-commission and Commission on Human Rights.[21] In 2001, both the UN General Assembly[22] and the World Health Assembly supported this stance.[23]

In its intervention at the Fourth Ministerial Conference of the WTO which adopted the Doha Declaration on TRIPS and public health, the WHO stated that "access to health care is a human right (...) includes access to health facilities, prevention, care, treatment and support, and of course access to medicines"[24].

In-depth work on access to health care as a human right began in 2002 and the "2003 Annual Report of the Department of Essential Drugs includes an explicit reference to access to medicines as a human right. The result of this development, the Strategy 2004-2007 of the Department of Essential Drugs, included among the new areas of work the promotion of access to medicines as a human right."[25]

In 2002 the Network for Monitoring the Impact of Globalization and TRIPS on Access to Medicines[26] was created in response to the decision of the World Health Assembly requesting the Director General to "cooperate with Member States, at their request, and with other international organizations in monitoring and analyzing the implications of international trade agreements on pharmaceuticals and health (...) in order to maximize the positive effects and mitigate the negative impact of these agreements."[27]

In 2003, the Department of Essential Medicines was restructured into two departments: the Department of Medicines Policies and Standards, and the Department of Technical Cooperation for Essential Drugs and Traditional Medicines - TCM; the latter being in charge of work in the field of intellectual property and access to medicines. At the same time, the Member States of the WHO urged "to take into account in bilateral trade agreements the flexibilities contained in the TRIPS Agreement and recognized by the Declaration on the TRIPS Agreement and Public Health adopted by the WTO Ministerial Conference (Doha, 2001)."[28] The TCM department for instance drafted in 2005 a letter sent by Dr. Jim Yong Kim, the former Director of the Department of HIV/AIDS at WHO (and current President of the World Bank) to the Indian Minister of Health and Family Welfare, expressing the concerns relating to the continuous availability of affordable drugs supplied by Indian firms to other developing countries. The recent 1st April 2013 decision of the Supreme Court of India on the Novartis case fully reproduced the Jim Yong Kim letter. The ruling by the Supreme Court of India dismissing the petition by Novartis AG is a historic decision with positive global implications. Novartis had challenged the interpretation given by the Indian Patent

[20] Committee on Economic, Social and Cultural Rights, General Comment No. 14 The Right to the Highest Attainable Standard of Health, 2000, E/C.12/2000/4, para. 43.
[21] Sub-Commission on the promotion and protection of human rights, Globalization and its impact on the full enjoyment of all human rights, 2001, E/CN.4/sub.2/Res/2001/5.
[22] United Nations General Assembly, Declaration of Commitment on HIV/AIDS, 2001, A/RES/S-26/2, para. 15.
[23] WHA 54.11, WHO medicines strategy
[24] Statement by the WHO in the WTO Ministerial Conference, Doha, Qatar, 2001.
[25] Antezana, F., Seuba X. op.cit. p.48.
[26] WHO, "Network for monitoring the impact of globalization and TRIPS on access to medicines", Meeting Report, Thailand, February 2001. Geneva: WHO, Health Economics and Drugs, EDM Series No. 11, 2002. Available from http://apps.who.int/medicinedocs/en/d/Js2284e/.
[27] WHA.52.19 Revised Drug Strategy.
[28] WHA 57.14: Scaling up treatment and care within a coordinated and comprehensive response to HIV/AIDS

Office to Section 3(d) of the Patents Act that seeks to prevent the grant of patents on non-inventive new forms of known medicines.

IV. ORIGIN OF THE TERM TRIPS "FLEXIBILITIES"

In the UNCTAD document cited earlier[29] C. Correa et al. spoke of the "room to manoeuvre" that TRIPS gives in order to formulate national public policies. According to one opinion, the term "room of manoeuvre" was too harsh for the diplomatic environment in the United Nations, therefore the WHO's red book spoke of "Margins of freedom"[30] (1997). Subsequently, in March 2001, in a document widely distributed in the six official WHO languages, the WHO adopted the term "safeguards"[31].

The European Communities, in June 2001, spoke of a "sufficiently wide margin of discretion"[32] in reference to the implementation of the TRIPS Agreement. A few months later, in November 2001, in the Doha declaration on TRIPS and Public Health the WTO referred to "the provisions in the TRIPS Agreement which provide flexibility". It was in June 2001, where the WHO, in a document authored by Carlos Correa analyzing the implications of the Doha Declaration, referred to the "flexibilities" of the Agreement.[33]

Today, there is wide consensus on the use of the term "flexibilities" in reference to mechanisms and provisions for the protection of public health in TRIPS.

V. COMMISSION ON INTELLECTUAL PROPERTY RIGHTS, INNOVATION AND PUBLIC HEALTH (CIPIH)

The Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH) was created in 2003 by means of a resolution[34] of the World Health Assembly. Member States of the WHO requested that the WHO prepare a report by independent experts regarding Intellectual Property, Innovation and Public Health, so as to continue and deepen the work already done in the report of the British Commission in 2002[35] on the same issue.

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[29] 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).

[30] Velásquez, G., Boulet P., "Globalization and Access to Drugs: Implications of the WTO/TRIPS Agreement", WHO/DAP/98.9, Geneva, November 1997, page 34.

[31] WHO Policy Perspectives on Medicines, "Globalization, TRIPS and access to pharmaceuticals", No. 3, (WHO, Geneva, March 2001), page 5.

[32] Communication from the European Communities and their member states to the TRIPS Council (IP/C/W/280), June 12, 2001.

[33] C. Correa, "Implications of the Doha Declaration on the TRIPS Agreement and Public Health", WHO/EDM/PAR/2002.3, Geneva, 2002, see the chapter entitled Flexibility in TRIPS, page 13.

[34] WHA Resolution, WHA56.26 Intellectual Property Rights, Innovation and Public Health.

[35] " Integrating Intellectual Property Rights and Development Policy", Report of the Commission on Intellectual Property Rights, London, September 2002.

The group of experts, chaired by Swiss ex-president, Ruth Dreifuss, was quite complex and difficult to manage as there were people from the industry and different conflict of interests arose. The situation was handled masterfully by Mrs. Dreifuss and at the end of 2006, the product of the group's work was presented to the WHA; the report on "Public Health, Innovation and Intellectual Property Rights"[36]. The said report contained 60 recommendations, the majority of which dealt with intellectual property, what countries can and should do in order to protect the health sector from new international trade rules.

The report recognized "the need for an international mechanism to increase global coordination and funding of medical R&D"[37] and recommended, among other things, the continuation of work for the adoption of a treaty on pharmaceutical R&D "to develop these ideas so that governments and policy-makers may make an informed decision".[38]

The report even suggests that the problem of access to medicines is not limited to developing countries. "This issue is important because even in developed countries, the rapidly rising costs of health care, including supplies of medicines, are a matter of intense public concern. In developing countries, and even in some developed countries, the cost of medicines, often not available through public healthcare systems, can be a matter of life and death."[39]

VI. THE GLOBAL STRATEGY AND PLAN OF ACTION ON PUBLIC HEALTH, INNOVATION AND INTELLECTUAL PROPERTY (GSPOA)

The United States took a forward stance in the face of the possibility that the World Health Assembly would possibly adopt this report. After complicated debates, an inter-governmental group was formed in order to analyze and propose what should be done with the recommendations of the CIPIH report, as in 2006 the WHA did not manage to adopt the report. The inter-governmental group was envisioned as a small group of around 10 countries represented by their missions in Geneva, but more than 100 countries attended the group's first meeting held at the end of 2006. Deliberations and negotiations took two years, from start to approval, in the 2008 WHA on "Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property".[40]

This two-year negotiation may be considered the most relevant and important negotiations that have ever occurred in the 65 years of the existence of the WHO, after the negotiation and the adoption of the convention against tobacco, (FCTC)[41]. It was especially interesting because the developed countries in the WHO were there with the "ghost" of the Mrs. Dreifuss report, particularly in light of what it already recommended, exploring the possibility of making an international treaty for pharmaceutical funding and research and

[36] "Public Health, Innovation and Intellectual Property Rights", Report of the Commission on Intellectual Property Rights, Innovation and Public Health, ISBN 92 4 356323 8, Geneva, 2006, 204 pages.
[37] Idem, p. 87.
[38] Idem, p. 91.
[39] Idem, p. 177.
[40] Resolution WHA61.21 "Global Strategy and Plan of Action on Public Health, Innovation and Intellectual property", Geneva, 2006.
[41] FCTC : Framework Convention on Tobacco Control.

development (R&D). Before the idea of a binding mechanism came about, the drafting of a non-binding resolution like resolution 61.21 on Global Strategy was a negotiation where every word and comma counted.

During the negotiation, developing countries pointed out that the document presented by the WHO Secretariat[42] as the basis of the discussion omitted aspects related to intellectual property. These aspects made up the central focus of the 60 recommendations of the report chaired by Mrs. Dreifuss on which the inter-governmental group was asked to give guidance.

It was evident that in the context of the negotiations the topic of intellectual property was the common denominator that crossed all the topics of the document proposed by the WHO Secretariat. Instead of admitting that each component of the proposed elements clearly contained aspects of intellectual property, the WHO created a separate item, element 5: "Application and management of intellectual property to contribute to innovation and promote public health"[43]. At the end there were eight elements and only one dealing with intellectual property.

The Global Strategy managed to approve various elements in its action plan[44], but there was a deadlock regarding element 5, which concerned the issue of intellectual property and various elements of the plan of action were placed in brackets. As a result, in 2008 the World Health Assembly created an expert working group to examine the issues of coordination and funding of medical R&D that was known as the EWG (Expert Working Group on R&D financing and coordination). The mandate of the EWG was to advise countries and the WHO, regarding the recommendations of the report by the expert group chaired by Mrs. Dreifuss. The report, as mentioned referred mainly to intellectual property and among other things, the possibility of a binding international treaty on R&D.

It is important to note that paragraph 2.3. (c) of the GSPOA made reference to a possible international treaty on R&D of new drugs as a topic on which the EWG should advise. Therefore, the negotiation and the adoption of an international instrument on medical R&D should be a key element in the implementation of the GSPOA. Despite the insistence of some members of the EWG, the group's report completely omitted any reference to the possibility of a binding convention or treaty, the main reason why the report was not adopted by the 2010 WHA.[45]

[42] WHO, Report of the IGWG First Session, 25 January 2007.

[43] Element 5 of Resolution WHA61.21 'Global Strategy and Plan of Action on Public Health, Innovation and Intellectual property ', Geneva, 2006.

[44] During a 'drafting group' that lasted an entire week during the World Health Assembly in 2008.

[45] Velasquez, G., Seuba X., Rethinking Global Health: A binding convention for R&D for pharmaceutical products , South Centre Research Paper No. 42, p. 10.

VII. CONSULTATIVE EXPERT WORKING GROUP ON RESEARCH AND DEVELOPMENT: FINANCING AND COORDINATION (CEWG)

Following the failure of the report by the Expert Working Group (EWG), a new group called the Consultative Expert Working Group on Research and Development: financing and coordination (CEWG) was created at the start of 2011. The aim of the CEWG was to deal with issues relating to intellectual property. On 18 November 2011, the Chairman of the CEWG announced that "the CEWG will recommend to the 2012 Health Assembly to commence formal intergovernmental negotiations for the adoption of a binding global instrument on medical R&D based on Article 19 of the WHO Constitution".[46]

The 65th World Health Assembly in 2012, which was supposed to analyze and adopt the recommendations of the CEWG report, met with a new obstacle as several industrialized countries opposed the commencement of negotiations for the adoption of a binding convention. The result of difficult negotiations was, once more, as was the case in 2006, the creation of an inter-governmental group[47] to analyze the CEWG recommendations and propose a solution.

The meeting of the new inter-governmental group took place from 26-29 November 2012. The industrialized countries proposed the establishment of a "global health R&D observatory within WHO's Secretariat in order to monitor and analyze relevant information on health R&D", the commencement of some pilot projects in the field of pharmaceutical R&D and "to convene another open-ended meeting of Member States prior to the Sixty-ninth World Health Assembly in May 2016, in order to assess progress and continue discussions on the remaining issues in relation to monitoring, coordination and financing for health R&D; taking into account all relevant analyses and reports, including the analysis of the report of the Consultative Expert Working Group on Research and Development: Financing and Coordination." However, it is difficult to understand that negotiations on resolving an urgent problem like the lack of pharmaceutical R&D for the production of accessible medicines must wait four years. It seems as if the protection of the pharmaceutical market is worth more than human life.

"Several Member States seem to support the establishment of a WHO-hosted global health R&D observatory. Such an observatory would be a positive first step. However, given the extent of the challenge, efforts that solely aim to improve monitoring of global health R&D and assist with priority-setting, are not enough. An observatory will not provide adequate coordination, increase sustainable financing or result in new medical tools that are needed. If this is the only outcome to result from more than ten years of deliberations it would be woefully inadequate".[48] At the ill-fated November 2012 meeting, industrialized countries including the US, members of the European Union, Japan and Switzerland conducted an assiduous campaign of attrition to weaken support for WHO's future work on the de-linkage

[46] Velásquez, G., Seuba, X., "Rethinking Global Health: A binding convention for R&D for pharmaceutical products", South Centre Research Paper No. 42, December 2011.
[47] Resolution WHA65.22 Follow up of the report of the CEWG on Research and Development: Financing and Coordination.
[48] See MSF, Open letter to WHO Member States at follow-up meeting on the report of the CEWG, signed by 60 NGO's and Organizations, 25 November 2012,

paradigm to decouple the costs of R&D from the price of health technologies in lieu of the current system of patent monopolies."[49]

The 2012 meeting of the Intergovernmental Group prepared a draft resolution to be revised by the WHO Executive Board -EB- in January, 2013. A draft resolution[50] that made no reference to the clear recommendation of the CEWG to start negotiations for the adoption of a treaty; a draft that was viewed by various observers and NGOs as "weak and unambitious"[51]. A draft resolution that was presented to the Executive Board in 2013 with a report attached[52] that recommended to the WHO EB, and the 2013 WHA, to adopt the draft resolution without discussion.

On Friday, 25 January 2013, the 132nd session of the WHO Executive Board "held a rich and heated discussion on the Director-General's report (EB132/21) of the proceedings of the open-ended meeting (26-28 November 2012) on the follow-up of the Report of the Consultative Expert Working Group on Research and Development: Financing and Coordination (CEWG).

Despite the recommendation of the inter-governmental group, and advice of its Chairman to adopt the resolution, at the January 2013 WHO EB, "the understanding reached at the end of Friday's lengthy debate (lasting around 90 minutes) on the CEWG was that the Executive Board would take note of EB/132/21 (containing the Report by the Director-General and draft resolution) and submit the document in open form to WHA66 for consideration along with a record of the EB's discussion of the item showing that there was no consensus reached. At WHA66, as confirmed by WHO's Legal Counsel, (…) WHO Member States can comment on the draft CEWG resolution including submitting textual changes to amend and strengthen the Organization's mandate to work on a de-linkage paradigm for biomedical R&D."[53]

VIII. ADVANCES IN THE IMPLEMENTATION OF A "GLOBAL STRATEGY"

Finally, it would be worth analysing what advances there have been in the implementation of the "global strategy" and its 25-page plan of action. The progress to date can be summarized in three points:

1) The "Patent Pool"[54], a timely initiative that constitutes one element out of many others that form the mandate given by WHA Resolution 62.21. Patent pools can facilitate equal access and make new treatments against HIV cheaper, and facilitate the development of new fixed-dose combinations suited to meet the treatment needs of developing countries. These patent pools can be made up of voluntary licenses by the patent holder, as is the present case with "Medicines

[49] Knowledge Ecology International, 26 January 2013
[50] EB132/21 Follow-up of the report of the Consultative Expert Working Group on Research and Development: Financing and Coordination
[51] http://www.msfaccess.org/content/joint-letter-132nd-who-executive-board-follow-report-cewg
[52] WHO Report of the open-ended meeting of Members States on the follow-up of the report of the Consultative Expert Working Group on Research and Development : Financing and Coordination, Geneva,
[53] KEI op. cit.
[54] http://www.medicinespatentpool.org/

Patent Pool" –MPP- created with resources from the Franco-Brazilian initiative, "UNITAID".

2) The second activity that has been developed in the Americas is called "Platform on Innovation" which PAHO has promoted in the region, is a type of "Pharmaceutical Facebook" – a virtual network to share information on various activities in the field of pharmaceuticals.
3) The third element in the implementation of a global strategy is the publication of a tripartite report by the WTO, WIPO and the WHO. On 5 February 2013, in a ceremony at the WTO, the three Director Generals of WTO, WIPO and the WHO launched the trilateral publication titled: "Promoting Access to Medical Technologies and Innovation", the fact that a publication regarding public health was launched at the headquarters of the WTO is a reflection of the increasing importance of public health issues in the context of WTO and WIPO, an issue on which the WHO has been the leader.

The study shows progress on the part of the WTO and WIPO since they talk about these issues without "taboo", however it does not give a complete picture of the extent to which WHO has led this issue over the past decade. Seventeen resolutions by the World Health Assembly adopted between 1996 and 2012 are cited in the report in a table on page 44 concerning intellectual property and health. These resolutions are of highly prescriptive character, for the secretariat and for countries on how to protect public health from the possible negative impact of new international trade rules. Despite numerous resolutions and publications in the last 15 years by the WHO on this issue, many of which are not mentioned in the report, the disclaimer of the document says 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 could give the wrong impression to the reader of this report that the WHO has no opinion on whether a compulsory license may, in special circumstances, facilitate access to drugs, or if an international exhaustion regime, that allows parallel imports from any country can reduce the cost of drugs and therefore contribute to access. The 17 WHA resolutions give a mandate to the WHO to engage, promote and defend mechanisms and policies in favour of access. Thus, it is important to ensure that the Trilateral Cooperation with WTO and WIPO does not lead the WHO to share a "neutral" vision, totally disengaged from its mandate of protection of health and putting business before health at the WHO. This would be contrary to the exemplary leadership from the WHO on "The Revised Drug Strategy", WHA 52.19 in 1999 or the "WHO Policy Perspectives on Medicines" published in 2001 that says: "National patent and related legislation should: Promote standards of patentability that take health into account. (…) Incorporate exceptions, trademark provisions, data exclusivity and other measures to support generic competition. Permit compulsory licensing, parallel importation and other measures to promote availability and ensure fair competition. Permit requests for extension of transitional period for TRIPS implementation, if needed and if

eligible. Carefully consider national public health interests before instituting TRIPS-plus provisions."[55]
As expressed by the three NGOs that addressed the Executive Board in January 2013, the Trilateral Report is a weak and unambitious document in which the WHO does not fully reflect the work it has done on these issues in accordance with its mandate.

The question that Member States of the WHO, international organizations with a clear vision regarding the priority of health such as UNDP or UNAIDS, or UNICEF, non-profit NGOs working on public health, the academia and all the sectors concerned with the promotion of health and access to medicines should ask what is the relevance and status of this report in the face of the 17 resolutions by the WHA giving a clear mandate that is not reflected in this document.

It would seem that while the debate that began in the early 2000s about which one comes first, the right to health or international trade rules, has been resolved in favour of the right to health, but in this trilateral publication, the mandate of the WHO to promote public health seems to have been subordinated to accommodate IP and trade interests.

The Trilateral Report is a report that describes what others have said on the issue, without any of the three organizations saying what they think. The 251 page document contains no recommendations, not even a conclusion, or any guidance. In comparison, the 2006 WHO report on Public Health, Innovation and Intellectual Property rights (CIPIH report), led by the former president of Switzerland, Ruth Dreifuss, contained 60 recommendations.

A Japanese saying goes: "what a man does not say is the salt of a conversation".

IX. A STEP BACKWARDS FOR THE WHO?

The "patent pool", the platform on innovation and the tripartite report that we have just mentioned, are the three elements that the implementation of the Global Strategy has been reduced to between 2010 and today. The WHO, however, since 2006, the date on which the 60 recommendation report was published, had been undertaking a series of activities under the mandate given by the resolutions adopted by the WHA since 1996[56].

The main activities that the WHO was undertaking before 2010 were:

- Training for officials from health, trade and industry ministries and patent offices, on intellectual property and health. This training was done for four consecutive years in the Americas at the University of Buenos Aires, in Africa at the University of Cape Town and in the University of Bangalore for Asian countries.

[55] WHO Policy Perspectives on Medicines No. 3, "Globalization, TRIPS and access to pharmaceuticals", Geneva, 2001, p.4.
[56] See Annex I.

Among the objectives of this course, were the following: a better understanding of the importance of applying intellectual property laws and policies in accordance with the rights of patients and public health; improve the knowledge of legislation as well as national and international legislation relating to intellectual property (including patents, trademarks and data protection); and to strengthen national capacity for the formulation and application of intellectual property policies in accordance with public health needs and patient rights. In the case of Latin America close to 100 participants from 19 countries (Argentina, Bolivia, Brazil, Chile, Colombia, Costa Rica, Cuba, Ecuador, El Salvador, Guatemala, Honduras, Mexico, Nicaragua, Panama, Paraguay, Peru, the Dominican Republic, Uruguay and Venezuela) attended. In Asia and Africa there was a similar level of participation.

- Another important aspect was training patent examiners from patent offices in developing countries. Between 2006 and 2010 workshops for national patent offices were conducted for more than forty countries. The development of a public health perspective in patent examinations is one of the main aspects in the work towards access to medicines.

  It is necessary to watch and analyze trends in the grant of patents for pharmaceutical products in order to respond to the growing concerns about the increase in the number of patents that protect variations of medicines or existing procedures while the number of patents for new molecular entities is diminishing. Those responsible for the formulation of policies on health as well as patent examiners should be aware that decisions regarding the grant of a patent (which is generally considered valid until the contrary is proven) may directly affect the health and life of people in the country where the patent is granted. The WHO undertook a study on the different categories of patent claims for pharmaceutical products with a view to guide the practice of patent offices.[57]

  The study suggested some mechanisms that can be adopted in order to incorporate public health perspectives in procedures for the granting of pharmaceutical patents. It proposed a combination of general directives for the evaluation of some of the common modalities of patent claims for pharmaceutical products and it suggested elements for the elaboration of directives that bear public health in mind and the examination of patents for pharmaceutical products at the national level in developing countries.

- For several years the WHO gave technical assistance to countries that were developing or reviewing their intellectual property laws. A substantial number of countries were assisted. In the last 3 years the WHO Secretariat has not reported that this type of activity has taken place.

  The report of one WHO mission in 2008, with the participation of the WTO, UNDP and UNCTAD, at the request of the Government of Thailand[58], is a good

[57] WHO - ICTSD – UNCTAD, "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/.

[58] See the most relevant points of this report in Annex III, Chapters II, III and V. Report published by the National Health Security Office of Thailand (NHSO), 2008.

example of the type of support that international organizations should give to countries that decide to use the flexibilities contained in the TRIPS Agreement.

Among the recommendations of this report were the following: In seeking greater access to essential medicines 1. (…) "the introduction and use of all possible cost-containment mechanisms and the use of TRIPS-compliant flexibilities (…) 2. The TRIPS Agreement contains a range of mechanisms and options to protect public health that countries can consider when formulating intellectual property laws and public health policies. 3. The use of compulsory license and government use provisions to improve access to medicines is one of the several cost-containment mechanisms that may be used for patented essential medicines not affordable to the people or to public health insurance schemes."[59]

- Between 2002 and 2009 the WHO, in its capacity as an observer on the TRIPS Council at the WTO, made several interventions on issues regarding access to medicines and particularly on the mandate of the Doha Declaration. An extract of the WHO's intervention of September 17, 2002 at the WTO TRIPS Council states:

> "WHO re-affirms its commitment to support WTO Members and the Council for TRIPS in finding an expeditious solution to this problem raised in Paragraph 6 of the Declaration.
>
> To this end, WHO has published a paper entitled, "Implications of the Doha Declaration on the TRIPS Agreement and Public Health."[60] This paper describes the features of a solution to the so-called "paragraph 6 problem" which are desirable from a public health perspective. These include: a stable international legal framework; transparency and predictability of the applicable rules in the exporting and importing countries; simple and speedy legal procedures in the exporting and importing countries; equality of opportunities for countries in need of medicines, even for products not patented in the importing country; facilitation of a multiplicity of potential suppliers of the required medicines, both from developed and developing countries; and broad coverage in terms of health problems and the range of medicines.
>
> Thus, the basic public health principle is clear: the people of a country which does not have the capacity for domestic production of a needed product should be no less protected by compulsory license provisions (or indeed other TRIPS safeguards), nor should they face any greater procedural hurdles, compared to people who happen to live in countries capable of producing the product. Among the solutions being proposed, the limited exception under Article 30 is the most consistent with this public health principle. This solution will give WTO Members expeditious authorization, as requested by the Doha Declaration, to

[59] Improving Access to Medicines in Thailand: The use of TRIPS flexibilities, Report of WHO Mission, Bangkok, 31 January to 6 February 2008.
[60] WHO/EDM/PAR/2002.3.

> permit third parties to make, sell and export patented medicines and other health technologies to address public health needs."

X. THE WAY FORWARD

In a little more than ten years the WHO has produced important technical material in the area of public health and intellectual property; by the 17 World Health Assembly resolutions, numerous analysis and guiding publications[61] with the aim of protecting access to health in light of new international trade rules, required by the WTO, and recently by free trade agreements (FTAs) and bilateral investment treaties (BITs).

In terms of technical assistance to countries regarding the use of TRIPS flexibilities, the WHO seems to have changed direction in the past 3 years, marked by closer collaboration with WTO and WIPO. The collaboration of the WHO with the WTO and WIPO is a good thing so long as the mandates given by the WHA resolutions are respected and put into practice. With respect to international trade and investment treaties, the WHO cannot have a "neutral vision"; its mandate is directed toward the perspective of public health in conjunction with the various WHA resolutions in recent years. By speaking of international trade rules and issues related to public health we are speaking of two different regimes; and on different levels - in the first instance we are talking about economic rules and regulations while in the latter case we are dealing with the right to health as a part of human rights.

It remains to be seen in the future if the Secretariat of the WHO and its Member States will view the work and support of countries in intellectual property and health as an opportunity than a problem to avoid, particularly in the case of a possible international treaty on the funding of pharmaceutical R&D, that may contribute to this specialized UN agency re-discovering its identity and "raison d'être" in the twenty-first century.

[61] See the list of WHO publications related to intellectual property and public health, in the Annex II.

ANNEX I[62]
RELEVANT WORLD HEALTH ASSEMBLY RESOLUTIONS

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

[62] WTO, WIPO, WHO, "Promoting Access to Medical technologies and Innovation", 2012, page 44.

ANNEX II
WHO PUBLICATIONS ON INTELLECTUAL PROPERTY AND PUBLIC HEALTH

1. WHO Task Force on Health Economics, "The Uruguay round and drugs", by Correa C.M., WHO/TFHE/97.1, Geneva 1997.

2. WHO and Civitas "Medicines and the New Economic Environment," Lobo F., and Velásquez G., eds. Madrid: Civitas and World Health Organization, 1998.

3. WHO, Health Economics and Drugs, EDM Series No. 7 (Revised). "Globalization and Access to Drugs: Perspectives on the WTO/TRIPS Agreement". by Velásquez, G. and Boulet, P., WHO/DAP/98.9, Geneva, 1999. Available from: http://apps.who.int/medicinedocs/en/d/Jwhozip35e/3.html.WHO.

4. WHO Policy perspectives on medicines. No.3 "Globalization, TRIPS and access to pharmaceuticals", Geneva 2001.

5. WHO. "Network for monitoring the impact of globalization and TRIPS on access to medicines." Meeting Report, Thailand, February 2001. Geneva: WHO, Health Economics and Drugs, EDM Series No. 11, 2002. Available from: http://apps.who.int/medicinedocs/en/d/Js2284e/.

6. WHO/South Centre, "Protection of Data Submitted for the Registration of Pharmaceuticals. Implementing the Standards of the TRIPS Agreement", by Correa, C. M. Geneva, 2002. Available from: http://www.southcentre.org/index.php?option=com_content&view=article&id=68%3Aprotection-of-data-submitted-for-the-registration-of-pharmaceuticals-implementing-the-standards-of-the-trips-agreement&catid=41%3Ainnovation-technology-and-patent-policy&Itemid=67&lang=en.

7. WHO/South Centre, "Protection and Promotion of Traditional Medicine. Implications for Public Health in Developing Countries", by Correa, C. M. Geneva, 2002.
Available from:
http://www.southcentre.org/index.php?option=com_content&view=article&id=74:protection-and-promotion-of-traditional-medicines-implications-for-public-health-in-developing-countries&catid=41:innovation-technology-and-patent-policy&lang=es.

8. WHO, Health Economics and Drugs, EDM Series No. 12 "Implications of the Doha Declaration on the TRIPS Agreement and Public Health." By Correa, C. M., Geneva, 2002. Available from: http://apps.who.int/medicinedocs/pdf/s2301e/s2301e.pdf.

9. WHO. 25 Questions & Answers on Health and Human Rights. Geneva: WHO, 2002. Available from : http://www.who.int/hhr/activities/en/25_questions_hhr.pdf.

10. WHO/AFRO. "Trade-Related Aspects of Intellectual Property Rights (TRIPS) and the Implementation of TRIPS Safeguards in Relation to Pharmaceuticals in the WHO

African Region". Summary Report of a Workshop, Zimbabwe. August 2001, Brazzaville, WHO: Regional Office for Africa, 2002.

11. WHO, Health Economics and Drugs, EDM Series No. 13, 2003. "Cost-containment Mechanisms for Essential Medicines, Including Antiretrovirals, in China." by Velásquez, G., Correa C. M., and Weissman R., Geneva 2003.

12. WHO Regional Office for the Eastern Mediterranean. "Report on the Consultative Meeting on TRIPS and Public Health". Cairo: WHO Regional Office for the Eastern Mediterranean, 2005.

13. World Health Organization. Health Economics and Drugs, TCM Series No. 18 "Remuneration Guidelines for Non-Voluntary Use of a Patent on Medical Technologies." by Love, J. Geneva, 2005.

14. WHO, "Public health, Innovation and Intellectual Property Rights. Report of the Commission on Intellectual Property Rights, Innovation and Public Health". Geneva, 2006. Available from: http://www.who.int/intellectualproperty/documents/thereport/SPPublicHealthReport.pdf.

15. WHO/South Centre "The Use of Flexibilities in TRIPS by Developing Countries: Can they Promote Access to Medicines?" by Musungu, S. F. and Oh C. Geneva, 2006. Available from: http://www.southcentre.org/index.php?option=com_content&view=article&id=70:the-use-of-flexibilities-in-trips-by-developing-countries-can-they-promote-access-to-medicines&catid=41:innovation-technology-and-patent-policy&Itemid=67&lang=es.

16. WHO-ICTSD-UNCTAD "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/.

17. WHO/PHI/2009.1 "Guide for the application and granting of compulsory licences and authorization of government use of pharmaceutical patents." by Correa, C.M., Geneva 2009.

18. WHO Regional Office for South-East Asia. "International Health and Trade, a reference guide", New Delhi, 2009.

19. World Health Organization (WHO) Regional Office for the Eastern Mediterranean and the International Centre for Trade and Sustainable Development (ICTSD), "Public Health Related TRIPS-Plus Provisions in Bilateral Trade Agreements: A Policy Guide for Negotiations and Implementers in the Eastern Mediterranean Region." by El Said, Mohammed. Cairo, 2010 Available at: http://ictsd.org/i/publications/99149/.

20. WHO Regional Office for South-East Asia. "Intellectual Property and Access to Medicines: Papers and Perspectives." World Health Organization, SEA-TRH, 2010. Available from: http://apps.who.int/medicinedocs/documents/s17521en/s17521en.pdf.
21. Bulletin of the World Health Organization, 1999, 77(3): 288-292. "Essential drugs in the new international economic environment." by Velásquez, G., and Boulet P. Available from: http://www.who.int/bulletin/archives/77(3)288.pdf.

22. Bulletin of the World Health Organization, 2001, 79(5): 461-470. "Study of the implications of the WTO TRIPS Agreement for the pharmaceutical industry in Thailand. by Supakankunti, S., et al.", Geneva, 2001. Available from: http://www.who.int/bulletin/archives/79(5)461.pdf.

23. Bulletin of the World Health Organization. "Ownership of knowledge – the role of patents in pharmaceutical R&D." by Correa, C. M. 2004, 82(10): 784-786. Available from: http://www.who.int/bulletin/volumes/82/10/784.pdf.

24. Bulletin of the World Health Organization, 2004, 82 (11). "Has the implementation of the TRIPS Agreement in Latin America and the Caribbean produced intellectual property legislation that favours public health?" by Costa Chaves, G., Oliveira M. A., Velásquez G., and Zepeda Bermudez J. Available from: http://www.who.int/bulletin/volumes/82/11/en/815.pdf.

25. Bulletin of the World Health Organization, 2006, Volume 84(5). "Implications of bilateral free trade agreements on access to medicines". by Correa, C. M., Geneva 2006. Available from: http://www.who.int/bulletin/volumes/84/5/399.pdf.

26. Bulletin of the World Health Organization. "Special Theme: Intellectual Property Rights and Public Health", 2006, 84(5), 337-424. Available from: http://www.who.int/bulletin/volumes/84/5/itmb.pdf.

27. Bulletin of the World Health Organization, 2006, 84(5): 360-365. "Managing the effect of TRIPS on availability of priority vaccines." By Milstein, J., and Kaddar M., Available from: www.who.int/bulletin/volumes/84/5/360.pdf.

ANNEX III
IMPROVING ACCESS TO MEDICINES IN THAILAND: THE USE OF TRIPS FLEXIBILITIES
Report of a WHO Mission, Bangkok, 31 January to 6 February 2008

In accordance with the terms of reference of the mission, this report provides technical information and policy options on the general rules and mechanisms available to countries for use of the flexibilities contained in the WTO TRIPS Agreement and other international agreements, in order to promote greater access to pharmaceutical products.

The report of the mission is not intended to make any evaluation or assessment of the use of TRIPS flexibilities in Thailand.

Although the mission met with the various stakeholders during its visit to Bangkok, the discussions were aimed at facilitating an understanding of the context and circumstances related to the granting of compulsory licences in Thailand, and identifying the appropriate technical and policy support required on the use of TRIPS flexibilities.

This report has been prepared under the responsibility of WHO. In the context of resolution WHA60.30, resource persons from UNCTAD, UNDP and WTO participated in the mission to provide technical and factual information with regard to the TRIPS Agreement.

Members of the mission:

Germán Velásquez, WHO/HQ (Team Leader)
Bill Aldis, WHO/SEARO
Karin Timmermans, WHO/SEARO
Cecilia Oh, UNDP
Kiyoshi Adachi, UNCTAD
Roger Kampf, WTO
Xavier Seuba, WHO temporary adviser, Pompeu Fabra University, Barcelona

Introduction

In the context of resolution WHA60.30, the Minister of Health of Thailand requested WHO, in collaboration with other competent international organizations, to provide technical and policy support on use of the flexibilities contained in the WTO TRIPS Agreement in order to promote access to pharmaceutical products.

WHO, in its Medicines Strategy (2004-2007), identified four key objectives; namely: the strengthening of national medicines policies; improving access to essential medicines; improving the quality and safety of medicines; and promoting their rational use. In order to ensure that national medicines policies are effectively implemented to achieve the objective of improving access to priority medicines, WHO has identified the need to support countries in

their efforts to use public health safeguards in international, regional and bilateral trade agreements.[63]

WHO's policy perspectives are informed by the following basic principles:

- "Access to essential medicines is a human right
- Essential medicines are not simply another commodity,
- TRIPS safeguards are crucial
- Patent protection has been an effective incentive for R&D for new drugs
- Patents should be managed in an impartial way, protecting the interests of the patent-holder, as well as safeguarding public health principles
- WHO supports measures which improve access to essential medicines, including application of TRIPS safeguards"[64].

Since 1997, resolutions of the World Health Assembly have provided WHO with a broad mandate in the area of intellectual property and access to medicines. More recently, resolution WHA60.30 of May 2007 requested the Director-General "to provide… in collaboration with other competent international organizations, technical and policy support to countries that intend to make use of the flexibilities contained in the agreement on Trade-Related Aspects of Intellectual Property Rights and other international agreements in order to promote access to pharmaceutical products".

Consistent with its mandate, WHO advocates to Member States the importance of the TRIPS flexibilities to protect public health and promote access to essential medicines and draws attention to the need to include them in national laws.

In accordance with the terms of reference of the mission, this report provides technical information and policy options on the general rules and mechanisms available to countries for use of the flexibilities contained in the WTO TRIPS Agreement.

II. Non-voluntary licences for government use: practical aspects and procedures[65]

Article 31 of the TRIPS Agreement regulates "other use of the subject matter without the authorization of the right holder", addressing what is commonly known as compulsory licensing. While, as was made clear in the Doha Declaration on the TRIPS Agreement and Public Health, the TRIPS Agreement leaves each Member free to determine the grounds on which compulsory licences can be granted, it does mention an number of possible grounds, including national emergency or extreme urgency, public non-commercial use, dependency of patents and to remedy anti-competitive practices.

This chapter specifically deals with the requirements and steps to be followed when granting a non-voluntary licence for government use. Similar requirements must also be complied with when granting non-voluntary licences under other grounds. Taking into account the provisions of the TRIPS Agreement, the granting of a non-voluntary licence for public non-commercial use would require a number of steps which are described below, and for which

[63] WHO Medicines Strategy: Countries at the Core (2004-2007) (WHO/EDM/2004.2).
[64] WHO Policy Perspectives on Medicines N° 3, Globalization, TRIPS and access to pharmaceuticals, March 2001 (WHO/EDM/2001.2).
[65] Cost-containment mechanisms for essential medicines, including antiretrovirals, in China (WHO/EDM/PAR/2003.6).

references to the Thai legislation are provided merely as an example of its national implementation.

Identify relevant patents

In most cases, pharmaceutical products are protected by a patent on the active ingredient (the main patent) and by a number of patents on formulations, manufacturing processes, new indications, etc. (secondary patents). It is advisable to include all relevant patents in a compulsory licence to allow freedom to operate with the needed product. Otherwise, the use of the invention under the compulsory licence may be blocked on the basis of allegations of infringement of secondary patents (as illustrated by the well-documented case of didanosine in Thailand almost a decade ago), making it necessary to resort, for instance, to alternative drug formulations, such as powder forms.

Explore possible sources of supply based on local production

The analysis to be undertaken should include:

- availability of technical resources for reverse engineering
- cost and duration of developing manufacturing processes and formulations
- the need for technology transfer
- good manufacturing practices and quality assurance of products made by local producers
- estimates of the investment required and of the marginal cost of production.

Identify possible sources of importation of the required medicine

The analysis to be undertaken should include:

- compliance with good manufacturing practices and product quality assurance by potential suppliers
- cost comparisons vis-à-vis local production
- prices of supply over time
- the sustainability of the exporter's supply.

Marketing approval

Registration is an important safeguard to ensure quality of the product. However, registration requirements may pose obstacles to the speedy distribution of needed medicines (see, for example, Chapter III, Bolar exemptions), hence, analysis of the scope of such obstacles and identification of the required remedial measures may be needed. Countries could consider creating a fast–track mechanism and/or giving priority to the evaluation and registration of a medicine that is considered urgently needed or important.

Request for a non-voluntary licence for government use[66]

A compulsory licence or 'non-voluntary licence' allows a government to authorize itself or a third party to use the subject matter of a patent without the consent of the right holder for

[66] Flynn, S. Thai Law on Government Use Licences. American University, December 2006.

reasons of public policy. A 'non-voluntary licence' authorizing the government itself to use a patented invention is known as a government use authorization. Article 31 of the TRIPS Agreement allows the grant of compulsory licences subject to certain conditions, and the Doha Declaration reaffirms that countries have "the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted".[67] These rights and freedom do not mean that compulsory licences are not regulated. States have to fulfil certain procedures and criteria in order to grant a non-voluntary licence.

It has to be noted that the TRIPS Agreement does not define the meaning of "public non-commercial use". However, the Vienna Convention on the Law of Treaties commands, as a general rule of interpretation, to interpret a treaty "in good faith in accordance with the ordinary meaning given to the terms" (Article 31). Following this rule, it has been argued that the meaning of "public non-commercial use" may be found in the nature of the transaction or the purpose of the use of the patent. Regarding the nature of the transaction, "non-commercial" may be understood as "not-for-profit" use, while, as far as the purpose of the use is concerned, "non-commercial" may refer to the supply of public institutions that are not functioning as commercial enterprises. The fact that the licence will be used to support a public interest programme may be sufficient grounds for justification.

Article 31 of the TRIPS Agreement makes the use of the subject matter of a patent without the authorization of the right holder, including use by the government, conditional on its admissibility under domestic law. In the case of Thailand, for instance, non-voluntary licences for government use can be granted on the basis of Section 51 of the Patent Act B.E. 2522 (1979), as amended by the Patent Act (No. 2) B.E. 2535 (1992) and the Patent Act (No. 3) B.E. 2542 (1999). Section 51 of Thailand's Patent Act recognizes the right of "any ministry or department of the Government", "by themselves or through others" to exercise any right conferred by the patent in order to carry out any service "for public consumption".

Section 51 specifically states:

> *"In order to carry out any service for public consumption or which is of vital importance to the defence of the country or for the preservation or realization of natural resources or the environment or to prevent or relieve a severe shortage of food, drugs or other consumption items or for any other public service, any ministry, bureau or department of the Government may, by themselves or through others, exercise any right under Section 36 by paying a royalty to the patentee or his exclusive licensee under paragraph 2 of Section 48 and shall notify the patentee in writing without delay, notwithstanding the provisions of Section 46, 47 and 47bis.*
>
> *In the circumstances under the above paragraph, the ministry or bureau or department shall submit its offer setting forth the amount of remuneration and conditions for the exploitation to the Director-General. The royalty rate shall be as agreed upon by the ministry or bureau or department and the patentee or his licensee, and the provisions of Section 50 shall apply mutatis mutandis."*

Licensing authority

[67] WTO Ministerial Conference, Declaration on the TRIPS Agreement and Public Health, adopted on 14 November 2001, WTO/MIN(01)/DEC/W/2, 20 November 2001, paragraph 5(b).

Under the Thai Patent Act, the Director-General of the Department of Intellectual Property is authorized to grant various types of compulsory licences. Complementing this, under Section 51, a public use licence may be also issued by "any ministry, bureau or department of the Government" by " themselves or through others."

Notice to the patent holder

Article 31 (b) of the TRIPS Agreement establishes as a general obligation to try to obtain authorization from the right holder on reasonable commercial terms and conditions when granting a non-voluntary licence. When such efforts are not successful, the use of the patent's subject matter without the authorization of the right holder can be permitted. The same article waives this obligation in cases of public non-commercial use and national emergency or other circumstances of extreme urgency. In cases of public non-commercial use, there is an obligation to promptly notify the title holder. In cases of national emergency or urgency, this notification is required as soon as reasonably practicable.

Section 51 of the Thai Patent Act requires that the licensing authority "shall notify the patentee in writing without delay, notwithstanding the provisions of Section 46, 47 and 47bis." The exemption from the requirements of Section 46, 47 and 47bis makes clear that the Government is not required to: (1) wait until "the expiration of three years from the grant of a patent or four years from the date of application," or (2) have "made an effort to obtain a license from the patentee having proposed conditions and remuneration reasonably sufficient under the circumstances".

In relation with the aforementioned notification, a communication to the patent holder should be sent. The TRIPS Agreement is silent on the content of this notification. However, regarding compulsory licences in general and extrapolating the practice in certain countries with regard to the request to the patent holder,[68] the notification may include:

- information about the requesting party
- the expected volume of production;
- the royalty to be paid
- the form of payment
- the intended mode of use of the invention
- quality controls
- trademark to be used, if any
- the duration of the licence
- the licensee's right to control sales for determination of royalties due
- the applicable law and jurisdiction in case of disputes.

Scope and duration of the licence

According to Article 31 (c) and (g) of the TRIPS Agreement, the competent department will have to define the scope of the licence and its duration. The scope and duration shall be limited to the purpose which led to its authorization, and the authorization shall be liable to be terminated if and when the circumstances which led to it cease to exist and are unlikely to recur. In the same vein, the Thai Patent Act lays down that "the scope and duration of the license shall not be more than necessary under the circumstances" (Section 50.1).

[68] WHO/EDM/PAR/2003.6, op. cit., p. 8.

It would be advisable for the scope to include all commercial and non-commercial uses of the relevant invention required to meet the purpose of the licence, and for the licence to last until the purpose which led to such granting so requires. In any case, authorization for such use should terminate if and when the circumstances which led to it cease to exist and are unlikely to recur. The fulfilment of this requisite can only be evaluated when a prudential period of time expires.

Royalties

Article 31 (h) of the TRIPS Agreement affirms that "the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization". The TRIPS Agreement allows Members "to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice" (Article 1). This is a broad authorization to design the mechanisms to implement TRIPS obligations, precluding the necessity to copy or follow the procedures that are in place in other countries.

Regarding royalties, it has to be taken into account that there are no internationally agreed criteria - and frequently, no national ones either - to set up the payable fee. This vacuum and the associated controversies not only affect government use licences, but also voluntary commercial licences, which are characterized by their variability. To reduce uncertainty and promote predictability in this regard, it is advisable to formulate explicit guidelines or criteria to determine the remuneration rate or royalty fee payable in the case of non-voluntary licences (see Chapter V).

The Thai Patent Act, for example, in Section 51 states that the ministry or bureau or department issuing the non-voluntary licence "shall submit its offer setting forth the amount of remuneration and conditions for the exploitation to the Director-General [of the Department of Intellectual Property]". The royalty rate and terms shall be "as agreed upon by the ministry or bureau or department and the patentee or his licensee", and the provisions of Section 50 "shall apply mutatis mutandis" (i.e. with necessary changes).

After the granting of the compulsory licence, *bona fide* negotiations could be undertaken with the patent holder to evaluate the fee for the exploitation of the patent. Generally, fees are expressed as a percentage of the net sales price of the product made under the licence (and not the patentee's own product), but other modalities can be adopted, for instance, a fixed sum per unit sold.

Commercial practice in voluntary licensing is to use royalties ranging between 2% and 5%, though they may be higher or lower in certain cases. There is some evidence available on the royalties determined by national authorities in Canada, the USA[69] and developing countries[70] for the granting of compulsory licences. (A full discussion on how various countries have chosen to establish royalty rates is set out in Chapter V.)

Factors that may be considered in negotiating the fee include: launch date of the product; possible substitutes; coverage and possible invalidity (total or partial) of the patent(s); pending challenges to the patent(s), if any; accumulated sales and recovery of R&D

[69] WHO/UNDP. Remuneration Guidelines for Non-Voluntary Use of a Patent on Medical Technologies (WHO/TCM/2005.1).
[70] See Chapter IV.

investment made by the patent holder; global and local market for the product (units and value); expected volume of production and price under the compulsory licence; royalties agreed upon in voluntary licences on the same or similar products; and the nations' economic and health situation.

Acceptance of the terms of the licence

The terms of the government use licence may be appealed by the title holder. Lacking an appeal, it will be legally understood that the licence's terms are accepted. The Thai Law does not expressly fix the period of time for the patent holder to accept or reject the terms of the licence for government use. However, this period is the same as that established for compulsory licences granted to remedy anti-competitive practices, dependent patents and the non-working of a patent (Section 50): should the parties fail to reach an agreement within the period prescribed by the Director-General, the Director-General will set forth the royalty and conditions, and this decision may be appealed to the Board of Patents within sixty days.

Determination of fee and conditions by the Director-General of the Department of Intellectual Property

Section 50 of the Thai Patent Act establishes that "if no agreement has been reached by the parties within the period prescribed by the Director-General, the Director-General shall fix the royalty and prescribe the conditions and restrictions as he deems appropriate" following a set of requirements also contained in Section 50.

Appeal

The relevant provisions in the TRIPS Agreement envisage that "the legal validity of any decision relating to the authorization of such use shall be subject to judicial review or other independent review by a distinct higher authority", and "any decision relating to the remuneration provided in respect of such use shall be subject to judicial review or other independent review by a distinct higher authority" (Article 31 (i) and (j)). These provisions must be read in conjunction with Article 44.2 of the TRIPS Agreement regarding injunctions. This article establishes that Members may limit the remedies available against government use licences to those related to the payment of remuneration. This means that the decision to use the patent, to grant a compulsory licence for "government use", need not be subject to injunctive relief (see also Chapter IV).

Section 50 of Thai Patent Act B.E. 2522 states that the decision of the Director- General of the Department of Intellectual Property on the terms and conditions of the compulsory licence is appealable to the Board of Patents within a period of sixty days. In turn, the Board's decision may be appealed to the Court also within sixty days, otherwise its decision will be final (Section 74). It should be noted that it is not the decision to grant a compulsory licence that it is appealable to the Board of Patents and later to the Court, but the terms of the licence.

The explanation is as follows.
Section 50, to which refers Section 51 when defining the requirements of the government use licence, states that "the decision of the Director-General made under the first paragraph of the Section is appealable to the Board within sixty days". The first paragraph of Section 51 deals with the conditions of the licence, but not with the decision to grant a licence, which is based either on Section 51 or Sections 46, 46bis or 47. This means that the evaluation of the grounds

to grant a licence exclusively concerns the Director-General of the Department of Intellectual Property (and, in the case of public non-commercial use, any ministry, bureau or department of the Government). Consequently, the possible appeal to the Board of Patents, and later on to the Court, does not suspend the execution of the compulsory licence, limiting possible judicial claims to the terms of the licence. Thus, the patent holder has no right to appeal the grounds for the decision to grant a government use licence but rather is limited to contesting the compensation due for the non-voluntary licence.

Other considerations

1) Patent holders (or their governments) may attempt to use legal measures, such as injunctions, to delay or prevent the execution of a non-voluntary licence.

2) It would also be useful to check the possible application of other instruments, such as bilateral agreements on investment (which often consider intellectual property as an "asset" subject to their rules) or free trade agreements with intellectual property provisions.

3) Article 31 (a) of the TRIPS Agreement lays down the requisite to consider on its individual merits the authorization of use without the consent of the patent holder. Each of the licences granted must be duly justified, which means that it is not possible to indiscriminately grant licences, but only after an assessment of their necessity has been undertaken.

4) The TRIPS Agreement also states that "such use shall be non-exclusive" (Article 31 (d)). This implies that the grant of a non-exclusive licence does not preclude the patent holder from exploiting the national market or exporting the patented product.

III. Other important TRIPS flexibilities to promote access to medicines

It is important to underline the fact that compulsory and government use licences are not the only flexibilities under the TRIPS Agreement that can have an impact on access to medicines. The range of measures that can be taken by governments under the TRIPS Agreement before a pharmaceutical patent is issued is often referred to as "pre-grant" flexibilities. "Post-grant" flexibilities, on the other hand, are policy options that, if incorporated into national law, are generally employed to address particular cases in the exercise of exclusive patent rights. The following non-exhaustive list of flexibilities is available to all WTO Members. It should also be noted that a number of these options are the subject matter of negotiations in preferential trade and investment agreements.

Pre-grant flexibilities

Many of the pre-grant flexibilities are intended to help ensure that the patent system confers upon an applicant the reward of exclusive rights for a true and genuine innovation. While certainly not exhaustive, the following flexibilities may be of particular interest to a developing country, such as Thailand, seeking to encourage the local production of low cost, high quality pharmaceuticals as one means to meet the objective of greater access to medicines.

First, the TRIPS Agreement is silent on the establishment of administrative procedures for patent opposition. Particularly relevant in this regard is the establishment of **observation**

procedures. Observation procedures provide third parties with the possibility to file an observation with the patent office on a pending patent application.

Third parties may use the observation procedures to claim, for example, that there has been insufficient disclosure by a patent applicant (Article 29 requires Members to provide for sufficiently clear and complete disclosure of an invention when submitting a patent application). An important additional flexibility in this regard is contained in Article 29.1, which allows Members to require the applicant to indicate the **best mode** known to the applicant for carrying out the invention.

Another important pre-grant flexibility is that of being able to **define the criteria for patentability**. Articles 27.1 states that inventions covering patentable subject matter need to be new, involve an inventive step, and capable of industrial application. None of these terms are defined in the TRIPS Agreement, however, and Members are generally free to define what constitutes a patentable invention. As an example, a strict novelty standard (which may stipulate that novelty should be judged internationally, rather than domestically), would narrow the scope of patentability. In the pharmaceutical context, new uses of an existing non-medical product for a medical purpose (first indications) and an existing medication for a new medical purpose (second indications) could conceivably be denied a product patent on grounds of lack of novelty. In this regard, it should be noted, for instance, that the new Indian Patent Act (2005) applies a strict standard on inventiveness (see also Chapter IV). Other countries apply relatively narrower or broader interpretations of the term "inventive step". It should be noted, importantly, that existing practice differs considerably from country to country with the result that patent protection received in one country does not necessarily mean that such protection is granted in another country.

The TRIPS Agreement authorizes Members to **exclude certain subject matter from patentability**. Article 27.3 (a) permits Members to exclude from patentability diagnostic, therapeutic and surgical methods for the treatment of humans or animals. Some countries treat discoveries of substances existing in nature, extractions/purifications from natural substances as excludable on the grounds that they do not constitute an "invention" under Article 27.1.

Post-grant flexibilities

As far as post-grant flexibilities and the patent application procedures are concerned, an important flexibility is the freedom given for Members to have a system where **opposition** of a patent is permitted. Under this option, a third party may file an opposition with the patent office after a patent has been granted, within a pre-determined period after the publication of the patent grant. The grounds for opposition are left open to each country, and may be the same as that for pre-grant observation procedures.

National laws may also permit **parallel importation** of patented products. This is related to a concept that needs to be addressed in the national law, namely that of the **exhaustion** of patent rights. Upon the first sale of a patented product, the patent holder loses the right to control the further distribution and resale of that particular product. Parallel importation involves the purchase of certain patent-protected products at lower prices and their importation into higher priced countries. These lower priced imports are not counterfeits, but merely lower-priced patented products that are purchased and subsequently re-sold by a third party. Parallel imports can be facilitated or hindered depending upon the type of exhaustion

regime a country decides to adopt. Under international exhaustion regimes, distribution rights available under the domestic patent will be exhausted by a first sale abroad in the same way as if that first sale happened domestically (thereby facilitating parallel imports). National exhaustion limits exhaustion to the domestic market and first sales of patented products outside the country will not affect the domestic patent (thereby inhibiting parallel imports).

In addition, a number of limited **exceptions to patent rights** exist under Article 30 and related TRIPS jurisprudence. Legally, this type of flexibility permits others to engage in activity that would normally be considered a patent right violation absent the consent of the right holder, due to overriding policy concerns. The two most notable ones, from the perspective of local pharmaceutical production and access to medicines, are the *scientific research/experimental use exception* (creating a safe harbour for scientific activities that might otherwise be blocked by patents – particularly for basic research and experimentation) and the *regulatory review (Bolar) exception*, which allows generic manufacturers to make use of a patented substance before the actual date of expiry of the patent for the sole purpose of obtaining marketing approval for that product.

An important flexibility exists in the compulsory licence system as well. Under Article 31 (f), pharmaceuticals produced under compulsory licence should normally be predominantly for the supply of the domestic market. The 2003 WTO Paragraph 6 Decision created a means by which it is possible to obtain a waiver from this general rule and therefore permits the production of a drug solely for export to needy countries. The TRIPS Agreement sets out, *inter alia*, detailed notification requirements for exporters and importers to avail of the waiver. In this regard, while least developed countries automatically qualify as an importing country under the system, developing countries may also take advantage of the system as importers if they can establish that they have insufficient or no manufacturing capacities.

A final post-grant flexibility that could potentially be of interest to Thailand is the use of **competition law** to address the abuse of the exercise of exclusive intellectual property rights. This flexibility is contained first in Article 8.2, which authorizes Members to adopt appropriate measures to prevent: the abuse of intellectual property rights by right holders, the resort to practices which unreasonably restrain trade, and practices which adversely affect the international transfer of technology, as long as such measures are TRIPS compatible. Further, Article 40.2 recognized the right of Members to take action against licensing practices or conditions pertaining to intellectual property rights which restrain competition and have adverse effects on trade and impede the transfer and dissemination of technology. The flexibility to use competition law and its related remedies (including fines, price regulation, compulsory licences (under Article 31(k)), etc.), requires not only enabling legislation that reflects the interrelationship between intellectual property and competition, but also professional and well-functioning competition authorities and interagency cooperation among the relevant authorities (in the case of pharmaceutical patents, between the patent and competition authorities and the ministry of health).

A comprehensive examination of Thailand's patent law vis-à-vis the above flexibilities is an exercise that is beyond the scope of this mission report. The mission recognizes that a number of flexibilities, such as the "best mode" requirement and pre-grant observation procedures, are already incorporated into Thai law. This report is meant only to list key TRIPS Agreement flexibilities that may be of interest to Thailand, with the understanding that the extent to which Thailand opts to deploy any of these flexibilities is a strategic one to be made by the Government.

IV. Guidelines and tools on the use of TRIPS flexibilities to promote access to medicines

Although the right of countries to make full use of the TRIPS flexibilities, including the granting of compulsory licences, for public health purposes is affirmed by the Doha Declaration on the TRIPS Agreement and Public Health, the absence of an appropriate national administrative and legal infrastructure and/or procedures to implement the compulsory licensing system may prevent effective exercise of this right. In this context, a number of issues were brought to the attention of the mission on which further guidance and technical support would be of use. These include the following:

- Guidelines and processes for public health-sensitive intellectual property rights management to ensure a clear and efficient decision-making process;
- A coherent approach that takes into account medium to long-term considerations for increasing access to medicines, including issues related to competition policy, technology transfer and local production;
- Relevant information and lessons learnt from experiences of other countries in the exercise and use of the TRIPS flexibilities;
- Access to relevant pharmaceutical patent data and determining the patent status of essential medicines; and
- Technical assistance, in particular, in relation to the determination and calculation of the remuneration rate for non-voluntary use of a patent.

This section below provides a summary of the options available to governments in terms of guidelines and tools on the use of TRIPS flexibilities.

Guidelines and processes for public health-sensitive management of intellectual property rights

It is acknowledged that the decision to grant compulsory licences and use other TRIPS flexibilities is often complicated and involves different stakeholders. It is therefore important to establish clear decision-making processes, including the determination or designation of the authorities or bodies charged with responsibility for the various stages of decision-making. It is noted that the TRIPS Agreement does not specify the nature of the authority or process that is mandated to grant compulsory licences or determine the level of compensation.

In this regard, WTO Members may designate the appropriate competent authority(ies) and process or system for the processing and granting of compulsory licences. It is noted that the systems vary in different countries, with some adopting administrative procedures and others a mixed system, where initial decisions relating to the grant of compulsory licences and compensation are made administratively and appeals are made to the judicial system.

The UK Commission on Intellectual Property Rights[71] in its 2002 Report identified some of the key features for such a system, as follows:

- legislation that fully exploits the flexibilities in the TRIPS Agreement for determining the grounds for compulsory licensing, as well as for non-commercial use by government;
- straightforward, transparent and fast procedures;

[71] UK Commission on Intellectual Property Rights. Integrating Intellectual Property Rights and Development Policy. London, September 2002.

- clear, easy-to-apply and transparent guidelines for setting royalty rates; and
- a procedure for appeals that does not suspend the execution of the compulsory licence or government-use provision.

Some of the specific features of an appropriate administrative system are discussed in further detail below.

A coherent approach

As described above, different authorities and/or bodies may be charged with the responsibility of ensuring the careful consideration of factors and requirements involved in the grant of compulsory licences. While these are not required under the TRIPS Agreement, it is also advisable to facilitate the consideration of the medium- to longer-term considerations relevant to ensure the effective and sustainable use of the TRIPS flexibilities as well as to meet the objectives of increased access to medicines. The introduction of an appropriate monitoring and data collection system to assess the impact of the use of the TRIPS flexibilities is an important consideration. Other considerations that may be made within or outside the designated decision-making process for compulsory licensing could include issues related to competition policy, technology transfer and local production, for example.

Country experiences and lessons learnt in the exercise and use of TRIPS flexibilities

As described in Chapter IV above, a number of countries, in the recent years, have used compulsory licences as one means of promoting access to medicines. Information is also provided on the use of compulsory licensing in developed countries, as well as the use of other TRIPS flexibilities by countries in the pharmaceutical sector. Information on the policy and legal measures adopted by other governments in the exercise of their rights in this area could provide useful lessons for others.

Determining the patent status of medicines

Accurate and up-to-date information about the patent status of pharmaceutical products is not always easily accessible or available in an easily understood form. This may stem from the lack of capacity and/or resources in national patent offices to administer the patent system (including managing effective search mechanisms) and to respond to the public health needs. The patent status of essential medicines is clearly a crucial factor in ensuring effective decision-making on use of TRIPS flexibilities.

Patent searches are complicated and highly technical endeavours. Searches are much more difficult where national patent data is not available electronically in robust form and is not incorporated in public or commercial databases. Moreover, patent information is generally searchable by technical description of the patented invention. In the case of pharmaceuticals, searches can be done on the chemical compounds, formulations or compositions related to the medicine but not on the brand-name (or generic name) of a product in which the invention is eventually incorporated. Although professional patent search companies are available, they are often expensive and may not present a feasible option for under-resourced agencies.

For this reason, the WHO Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH) had recommended the creation of a patent database for key pharmaceutical products, maintained by international organizations such as WHO and WIPO, in order to

increase transparency of the patent system and to remove potential barriers to availability of and access to products and to facilitate informed decision-making[72]. WHO, UNAIDS and MSF jointly published, in 2004, a patent status analysis of 18 ARV and HIV-related medicines in 29 developing countries, which included the priority patent numbers and the corresponding patents in these countries. The document provides patent data related to the chemical compound, key formulations or modifications of the selected medicines, and where available, patent data on the combination of the selected medicines with other medicines[73]. WHO has also initiated a project[74] to develop a methodology to obtain patent data from public sources, including from the databases maintained by the drug regulatory agencies of the US and Canada, which makes publicly available the lists of medicines approved for marketing and the patents claimed as relevant to them. This patent information provides an initial list of potentially relevant patents from which searches can be made to identify corresponding application and patent documents in other countries. It should however, be noted that there are limitations to this methodology; the most notable being that it will not work for drugs or drug combinations not marketed in the US or in Canada.

Developing a public health perspective for the examination of pharmaceutical patents

Although only a small number of new chemical entities are approved annually, the number of patents applied for protection of pharmaceutical products are increasing. In the circumstances, the criteria applied to examine and grant pharmaceutical patents are extremely relevant for public health policies, and not only a matter of concern for patent and industrial policy. In this specific context, Thailand has been very much involved in the WHO/UNCTAD/ICTSD project to examine the various categories of patent claims for pharmaceutical products. The project suggests some of the mechanisms that may be adopted to incorporate public health perspectives in procedures for the granting of pharmaceutical patents. It proposes a set of general guidelines for the assessment of pharmaceutical patent claims, and suggests elements for development of public health sensitive guidelines for the evaluation and review of pharmaceuticals patents at the national level in developing countries[75].

Guidelines for determining adequate remuneration for compulsory licensing

Article 31 (h) of the TRIPS Agreement provides that "the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization". Most national legislation adopts a similarly flexible approach, using terms such as "reasonable" or "adequate", including the Thai legislation which provides that "the remuneration fixed shall be adequate for the circumstances of the case"[76].

There are a number of considerations related to the determination of the remuneration rate. The term "adequate remuneration" is not defined in the TRIPS Agreement, and WTO Members are free to determine their approach. The TRIPS Agreement allows Members "to determine the appropriate method of implementing the provisions of this Agreement within

[72] CIPIH Report recommendations 4.16 and 4.17. op. cit.
[73] Determining the Patent Status of Essential Medicines in Developing Countries. WHO/UNAIDS/MSF (WHO/EDM/PAR/2004.6).
[74] See Communication from WHO to WTO TRIPS Council, Technical Cooperation Activities: Information from Other Intergovernmental Organizations – World Health Organization (WHO), IP/C/W/478/Add.4, 23 October 2006.
[75] Guidelines for the examination of pharmaceutical patents: developing a public health perspective. Working Paper. Geneva, WHO/ICTSD/UNCTAD, January 2007.
[76] Section 50.5, to which refers Section 51, on compulsory licences in the public interest.

their own legal system and practice" (Article 1). This is a broad authorization to set up the appropriate mechanisms to implement TRIPS obligations. There is however, no internationally agreed criteria for determining the adequate rate of remuneration[77]. Similar issues exist in the case of voluntary commercial licences.

State practice regarding the determination of "reasonable" royalties or "adequate" remuneration is extensive and varied. A number of royalty systems have also been adopted or proposed in recent years, and establish useful frameworks for consideration. The evidence of compensation for voluntary technology licensing in the private sector also provides an important context for making determinations of remuneration rates. These different options are documented in the WHO/UNDP publication, *Remuneration Guidelines for Non-Voluntary Use of a Patent on Medical Technologies*[78], and can be summarized as follows:

i) The remuneration rates paid by developing countries in recent cases of compulsory licensing. They range from the aforementioned 0.5% of Indonesia to a royalty rate of 4% in Malaysia.

ii) The UNDP royalty guidelines for compulsory licences, which are simple and predictable, contributing to ease the non-voluntary licensing process. The standard UNDP royalty is 4% of the price of the generic product, which can be raised or reduced by 2% depending on a set of circumstances, such as the therapeutic value or the government contribution to the costs of R&D.

iii) The Canadian approach, as set out in the Use of Patented Products for International Humanitarian Purposes Regulations (P-4 - SOR/2005-143)[79], establishes a sliding scale of 0.02% to a maximum of 4% royalty rate on the price of the generic product, based on the rank of the importing country in the United Nations Human Development Index (UNHDI). For most developing countries, the royalty rate would be less than 3%. The formula is: add 1 to the number of countries on the UNHDI, divided by the number of countries on the UNHDI, multiplied by 0.04. This rate is then applied to the generic sales price. The application of this formula to Thailand, 79 in the 2007/2008 UNDP Index, results in a 2.259% rate.

iv) The Japanese Patent Office guidelines for setting royalties on government-owned patents. The standard royalty under these guidelines ranges from 2 to 4%, but it can be increased or decreased by as much as 2%, resulting in a range of 0 to 6%. The criteria to determine the precise rate are diverse, such as the public interest in working of the patent, the importance of the patented invention to the final product or the novelty of the product.

A framework for remuneration

In determining appropriate policies and practices for determining reasonable royalties or adequate remuneration for the manufacture or sale of a medicine, countries should consider approaches that address practical concerns regarding the administration of a system, as well as policy objectives. Two factors can be considered in establishing systems for determining remuneration in compulsory licensing cases.

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[77] "There is wide variation in the way responsible government agencies and courts have set the amount of remuneration awarded to patent holders when patents have been subject to compulsory licensing". Scherer, FM. The Economics of Compulsory Drug Patent Licensing, Paper presented at the World Bank, 2 June 2003.

[78] (WHO/TCM/2005.1), op. cit.

[79] Use of Patented Products for International Humanitarian Purposes, SOR/2005-143, available on: http://laws.justice.gc.ca/en/p-4/sor-2005-143/text.html

1. the system of setting remuneration rates should not be overly complex or difficult to administer, taking into account the capacity of the government managing the system. Guidelines will reduce complexity and provide guidance for adjudicators, as well as increase transparency and predictability. Such guidelines, or any system for setting remuneration for compulsory licensing, should anticipate and address the need to divide royalty payments among various patent holders when the product is subject to multiple patents.
2. the amount of the remuneration should not present a barrier for access to medicines. Where a compulsory licence is issued on a pharmaceutical product, the purpose will be to lower price and improve access. Remuneration mechanisms should be designed so as to assist rather than defeat this purpose.

For countries able and willing to make somewhat more complex determinations of royalties, a range of appropriate factors should be assessed, though not all are required, and not all will apply in any given circumstance. These include but are not limited to:

- therapeutic value of the medicine, including the extent to which it represents an advance over other available products;
- the ability of the public to pay for the medicine;
- actual, documented expenditures on development of the medicine;
- the extent to which the invention benefited from publicly funded research;
- the need to respond to public health exigencies;
- the importance of the patented invention to the final product;
- cumulative global revenues and profitability of the invention; and
- the need to address anti-competitive practices.

Final remarks

1. In seeking greater access to essential medicines, national authorities may consider the full range of mechanisms available to contain costs of essential medicines and examine how the various tools may complement one another.
2. A sustainable system for the funding of medicines could be based on 3 main components: 1) the creation or enhancement of a national/social health insurance or of medicine prepayment mechanisms; 2) the introduction and use of all possible cost-containment mechanisms, and 3) the use of TRIPS-compliant flexibilities. The TRIPS Agreement contains a range of mechanisms and options to protect public health that countries can consider when formulating intellectual property laws and public health policies.
3. The use of compulsory licence and government use provisions to improve access to medicines is one of the several cost-containment mechanisms that may be used for patented essential medicines not affordable to the people or to public health insurance schemes.
4. WHO supports measures which improve access to essential medicines, including application of TRIPS flexibilities.

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