



**Pan American
Health
Organization**



*Regional Office of the
World Health Organization*

REPORT OF THE WORKING GROUP

**TRADE RELATED ASPECTS OF INTELLECTUAL PROPERTY
RIGHTS (TRIPS)**

AND

ACCESS TO MEDICINES

Focusing the Analysis in the Americas

Managua, Nicaragua, 14-16 April 2004

Authors and Editors

The content and the opinions expressed in this report are the exclusive responsibility of the members of the Working Group on TRIPS and Access to Medicines, convened by the Pan American Health Organization (PAHO)/ World Health Organization (WHO) in Managua, Nicaragua, 14 -16 April 2004.

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Acronyms and Abbreviations

ANVISA	National Health Surveillance Agency (Brazil)
AUGE	National Plan for Universal Access with Explicit Guarantees, Chile
CAFTA	Central American Free Trade Agreement
CCSS	Social Security Institute of Costa Rica
EFTA	European Free Trade Association
HIV/AIDS	Human Immunodeficiency Virus/Acquired Immunodeficiency Syndrome
CIPR	Commission on Intellectual Property Rights of the United Kingdom
IMS	IMS Health
MIFIC	Ministry for Development, Industry and Commerce, Nicaragua
MOH	Ministry of Health, Nicaragua
NGO	Non-Governmental organization
OTC	Over-The-Counter
PAHO/WHO	Pan American Health Organization/ World Health Organization
SMA	Mutually Agreed Upon Solution
TB	Tuberculosis
TRIPS	Trade-Related Aspects of Intellectual Property Rights
USA	The United States of America
WTO	World Trade Organization

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The Context of TRIPS and Access to Medicines

Expanding access to essential drugs and other basic public health supplies is a global priority and should be viewed within the context of the importance and recognition of the right to health for all¹. Compliance with the global mandates presented in the United Nations Millennium Declaration, September 2000, and the adoption of the priority public health goals will require access to essential public health supplies, specifically for HIV/AIDS, TB, and malaria. Furthermore, Target 17 of the Millennium Development Goals explicitly highlights the need to “provide access to ... essential drugs in developing countries.”

But the problem of access to medicines is not only limited to HIV/AIDS, TB, and malaria, although these diseases have attracted the most attention from international organizations, donors, and the general public. Millions of people, especially in the developing world, do not have access to existing medicines that are safe, effective, and relatively inexpensive, and that can save lives and prevent unnecessary suffering.

The price of medicines is only one of the many reasons for lack of access; what is clear is that the debate surrounding the effects of patents on prices and access, and, in the final analysis, the impact on public health, is one of the most contentious and difficult to resolve².

The TRIPS Agreement (Trade Related Aspects of Intellectual Property Rights) requires WTO (World Trade Organization) Member Governments to adopt and amend national laws to comply with the basic norms governing the protection of intellectual property. However, it also provides for the enactment of certain safeguards (for example, use of patents by governments; compulsory licensing; parallel imports; and other exceptions to exclusivity rights) that can void or limit the rights of patent holders under certain conditions. In fact, such measures have been introduced by developed countries in order to balance intellectual property rights with the public interest, encouraging competition, protecting consumers and, in the case of medicines, promoting access to affordable medicines by substituting expensive products with generics.

In the Region of the Americas, the amendment of national intellectual property laws has been dictated primarily by the need to ensure that national legislation is compliant with TRIPS. However, a number of bilateral and regional free trade negotiations and agreements have recently been initiated that go beyond TRIPS in protecting the rights of innovators, and establishing regulations that imply additional restrictions on access to medicines in the countries of the Region.

¹ Statement by WHO to the United Nations Human Rights Commission, point 10 on the agenda, Economic, Political and Cultural Rights, Geneva, 1 April 2003.

² WHO Discussion Document: For the 110th Inter-Parliamentary Union Assembly, Mexico (19-23 April 2004).

Working Group on TRIPS and Access to Medicines

Within this context, PAHO/WHO organized a Working Group meeting on TRIPS and Access to Medicines, with the participation of experts from the Region of the Americas. The purpose of the meeting was to formulate a series of recommendations for countries to facilitate the incorporation of TRIPS provisions when modifying intellectual property legislation, through global, multilateral or bilateral trade agreements, emphasizing the importance of public health and access to medicines.

The issues addressed in this report should be considered within the broader framework of developing and implementing medicines policy, as part of national health policy, which ensures access to and the rational use of essential drugs. The policy development process requires the participation of all stakeholders to strike a balance between the different approaches and competing interests, while recognizing at the same time that health and economic conditions differ in each country of the Region.

Recommendations of the Working Group

Based on the analysis of the experiences presented at the meeting, a number of lessons can be drawn that may guide countries of the Region in the development of a coherent strategy in trade negotiations, and in the modification or review of intellectual property legislation, as well as in implementation and monitoring.

The summary recommendations of the Working Group are presented below, grouped in three sections:

1. General recommendations on negotiating international trade agreements.
2. Specific recommendations on issues relevant to health in trade agreement negotiations.
3. Additional recommendations to improve access (unrelated to trade agreements).

The Recommendations of the Working Group are presented, taking into consideration the analyses, conclusions and outcomes of:

- The Declaration of the Ministerial Conference in Doha, Qatar, November 2001, on the TRIPS Agreement and Public Health which represents a major contribution to achieving public health objectives.
- The report of the Commission on Intellectual Property Rights of the United Kingdom (CIPR), which concluded activities in 2002, and which highlighted the need for developing countries to draft legislation and develop regulatory frameworks consistent with their own policy interests.
- The Commission on Intellectual Property Rights, Innovation, and Public Health (CIPRH), WHO.
- The Trade Promotion Authority (TPA) amendment of the Trade Act of 2002 (section on objectives for intellectual property negotiations), which stipulates that new trade agreements negotiated by the United States shall respect the Doha Declaration on TRIPS and Public Health.

1. General recommendations on negotiating international trade agreements:

The recommendations presented below are classified according to the subject they address: a) Negotiation and Agreements, b) Legislation, and c) Implementation and Monitoring. Each recommendation indicates to whom it is directed: Government, Health Sector and International Organizations. They are also identified as recommendations relating to the process (P) or the content (C) of the agreements or laws.

Issue 1: Negotiation and Agreements

RECOMMENDATION	DIRECTED TO	TYPE
1. In negotiating bilateral or multilateral trade agreements that have health implications, the health sector should participate and provide significant technical input, within the framework of the Doha Declaration.	Government	P
2. Ensure that treaties consider all the recommendations listed under the headings 'Negotiation and Agreements,' 'Legislation,' and 'Implementation and Monitoring,' and not just the recommendations listed under 'Legislation.'	Government	C

RECOMMENDATION	DIRECTED TO	TYPE
3. Broadly disseminate the meaning of “TRIPS-Plus” and its implications for access to medicines.	Health Sector, Intellectual Property Negotiators, and International Organizations	P P
4. Do not accept provisions that exceed the provisions of the WTO TRIPS Agreement.	Government	C
5. Conduct independent research into the impact of TRIPS on access to medicines, utilizing indicators such as price variations, generic drug entry to the market, the availability of orphan drugs, the increase or reduction in technology transfer, the level of direct foreign investment and public/private expenditures on medicines, changes in the balance of trade, and access to medicines by population group. To this end, it is proposed that PAHO, in partnership with other agencies, prepare a basic model for conducting these studies.	International Organizations and Health Sector	P
6. Inform countries about positive steps taken by some countries that could serve as a foundation in the negotiation of bilateral or multilateral trade agreements. For example, the U.S. negotiating team, by Congressional regulation, must respect the Doha Declaration in trade agreements that the United States enters into with other countries.	International Organizations	P

RECOMMENDATION	DIRECTED TO	TYPE
7. Establish transparency in these negotiations. The texts being negotiated should be disclosed during negotiations and not only after they have been concluded.	Government	C

Issue 2: Legislation

RECOMMENDATION	DIRECTED TO	TYPE
8. Include the safeguards provided for in TRIPS (parallel imports, compulsory licenses, “Bolar” provision, etc.) in intellectual property law.	Government	C
9. Insert clauses into national legislation that prevent abuse by patent holders, as in Article 8.2 of TRIPS.	Government	C
10. Promote information exchange between countries on patent legislation and trade agreements, highlighting positive provisions that help improve access to medicines and that can be applied in other countries.	Governments, International Organizations	P

Issue 3: Implementation and Monitoring

RECOMMENDATION	DIRECTED TO	TYPE
11. Develop the necessary regulatory and production capacity (if feasible) for the utilization of compulsory licenses. This has been an important negotiating tool both in developing and developed countries: for example, in Brazil (medicines for HIV/AIDS) and in the United States (for anthrax, (Ciprofloxacin)). New trade agreements should not restrict their use.	Governments	P
12. Request that PAHO prepare a glossary that includes the meaning of the provisions in TRIPS in order to standardize their interpretation in trade negotiations.	International Organizations	C
13. Establish mechanisms for ongoing monitoring of the impact of IP legislation and trade agreements on access to medicines.	Governments and International Organizations	P
14. Instruct officials in patent offices in the application of high standards of patentability to avoid the granting of evergreen patents and spurious or frivolous patents ³ .	Government	P

³ According to the U.S. Federal Trade Commission, in order to promote innovation a balance should exist between patent policy and competition policy. If one of these policies exerts a greater influence over the other one it can delay instead of promote innovation.

RECOMMENDATION	DIRECTED TO	TYPE
15. PAHO could assist in the organization of seminars to inform and train country negotiating teams about the effect that specific Intellectual Property provisions could have on access to medicines. These seminars should be held prior to the start of negotiations.	International Organizations	P

2. Specific recommendations on issues relevant to health in trade agreement negotiations

PROVISION	RISK	RECOMMENDATION
<p>Extensions of patent due to unjustified delays attributable to the government.</p>	<p>This is TRIPS-Plus: TRIPS does not provide for such extensions. It delays entry of generic medicines to the market.</p>	<ul style="list-style-type: none"> • Maintain the TRIPS provisions. • Evaluate compensation alternatives that do not involve patent extensions. • If extensions are to be accepted, permit them using Chile’s example, which establishes longer periods in granting a patent, before an extension can be authorized. • Establish that the effective patent, including any extension that is granted, shall not exceed a period determined by each country, as in U.S. law, for example. • In new agreements, establish that delays occurring due to the patent holder will not constitute justification for granting of an extension.
<p>Limitations on the use of compulsory licenses</p>	<p>This is TRIPS-Plus: It restricts Article 31 of TRIPS, a flexibility ratified in the Doha Declaration. It eliminates an important negotiating tool and instrument for resolving problems regarding access to medicines.</p>	<ul style="list-style-type: none"> • Maintain the text of Article 31 of TRIPS. It should be argued that the Doha Declaration, and the Trade Promotion Authority, defend the use of flexibilities. Chile and CAFTA maintain the use of compulsory licenses.

PROVISION	RISK	RECOMMENDATION
<p>Establishing marketing exclusivity under the guise of data protection. New trade agreements establish 5 or <u>at least</u> 5 years of data protection. The United States establishes 5 years in its legislation.</p>	<p>Data exclusivity periods can be extended even when the medicine cannot be patented, significantly delaying the introduction of generic medicines to the market.⁴</p>	<ul style="list-style-type: none"> • If possible, maintain the wording found in Art. 39.3 of the TRIPS Agreement. • If exclusivity is accepted through data protection, the protection period should be shorter than the patent period, permitting use of the “Bolar” exception. • If it must go further, do not accept more than 5 years. Do not accept wording that says “at least” 5 years. • The protection period should go into effect when the molecule is first registered with health authorities in any part of the world. Companies must have a public record of all such protections in order to confirm the date of first registration. • Do not permit consecutive periods (e.g. Chile). • If possible, add that extensions to this period will not be accepted. • Define the concept of ‘new chemical entity’ clearly and restrictively. It should not include, for example, new uses, dosages and forms of administration.

⁴ The TRIPS Agreement provides only for the nondissemination of data by government authorities to prevent its unfair commercial use. It does not establish a period of exclusivity. In some countries, more than one data protection event per drug have been recorded, which means that the stipulated period can be extended. Some recent agreements provide for consecutive application of the 5 years; for example, Singapore and CAFTA. Chile opposed consecutive periods. In the case brought by Argentina and the United States before the WTO, an agreement was reached to differ over the interpretation of this article in the TRIPS Agreement.

PROVISION	RISK	RECOMMENDATION
Elimination of restrictions on patentability ⁵	<p>Delay in the introduction of bio-generic products. Due to high cost, access to medicines produced using biotechnology may represent a serious problem in the future.</p> <p>Art. 27 of TRIPS excludes plant and animal patentability. But several of the recent agreements eliminate the restriction on patentability of plants and/or animals.</p>	<ul style="list-style-type: none"> Do not accept the elimination of restrictions on patentability. Maintain Article 27 of the TRIPS Agreement.
Condition drug registration on whether or not a	Problems and delays in the introduction of generic medicines.	<ul style="list-style-type: none"> Do not condition drug registration on whether or not a patent exists (Linkage).

⁵ Article 27 of the TRIPS Agreement places certain restrictions on patentability, for example: diagnostic methods, and plants and animals other than microorganisms and microbiological processes. New trade agreements eliminate the restriction on patentability for plants and/or animals.

PROVISION	RISK	RECOMMENDATION
patent exists (Linkage). ⁶		
Restrict or eliminate parallel imports	This eliminates the possibility of taking advantage of lower prices in other countries.	<ul style="list-style-type: none"> • Maintain this TRIPS flexibility using the Doha Declaration and the TPA as arguments: preserve the principle of international exhaustion of patent rights.
Restrict or eliminate grounds for patent revocation. ⁷	Maintains patents that, due to lack of exploitation or other grounds, could be revoked.	<ul style="list-style-type: none"> • Do not restrict revocation only to the reasons for which the patent was granted. • Include the wording on patent revocation set forth in NAFTA.
Restrictions or elimination of the exceptions that	Delays in generic drug entry to the market.	<ul style="list-style-type: none"> • It is important for the “Bolar” provision to be adopted specifically in new trade agreements and in countries’ national laws.

⁶ This is not part of the TRIPS Agreement. In many countries, it is being requested that this provision be established automatically so that the health authorities immediately oppose granting approval to a generic drug if the drug is patented. In the United States linkage is not automatic: the patent owner is informed that there is a request for the approval of a generic drug, and he has 45 days to begin proceedings against the applicant. If the patent owner does not act, the health authority can give authorization.

⁷ New agreements only permit patent revocation if the reasons for granting it were not valid. NAFTA stipulates that a patent can be revoked if the use of compulsory licenses has not solved the problem of lack of exploitation of a patent. This is an important negotiating instrument.

PROVISION	RISK	RECOMMENDATION
facilitate early marketing of generic medicines. “Bolar” provision⁸		

⁸ The “Bolar” provision permits development of the technological process while the patent is in effect with the purpose of obtaining registration from the health authority in order to market the product immediately upon expiration of the patent. This has been confirmed by the panel between the European Union and Canada where it was ruled that the “Bolar” provision conforms to the TRIPS Agreement.

3. Additional recommendations to promote access

The comparison and evaluation of information, and the development of strategies promoting access, is hampered by the significant differences that exist throughout the region of the Americas in medicines terminology and regulation, particularly with regard to generic medicines. It is requested that PAHO/WHO conduct a situation analysis with a view to developing a proposal that, in respecting national specificities, facilitates the comparison and consolidation of information and the sharing of experiences.

Differential pricing policies, applied individually by some companies, do not constitute an adequate, sustainable response to the problems of access to patented medicines in low-income countries, due to the lack of transparency, predictability, and equity in their determination. It is recommended that international organizations, and especially WHO and the WTO, resume the initiative launched in 2001 at the Workshop on Differential Pricing and Financing of Essential Drugs, held in Høsbjør, Norway, in order to seek well-grounded, transparent, and sustainable options, as well as objective mechanisms for setting prices using mutually agreed equity based criteria.

It is also recommended that governments and international organizations work together to improve drug supply management (procurement, price negotiation, supply, production, among other components) as one strategy for improving access to medicines. In the first phase, the partners should move to harmonize the essential drug lists and quality criteria between countries; guarantee financing; remove legislative barriers; and strengthen human resource capacity.

The impact of policies adopted by countries of the Region in the liberalization of medicine prices should be documented and evaluated. Pricing models used should be characterized, and mechanisms for price regulation identified that promote health system sustainability, especially in cases in which higher drug expenditures compromise the viability of the system.

Finally, the experiences of countries, where free trade agreements limit the capacity to regulate prices and in general, control medicine expenditures, should be documented.
