Center for International Environmental Law

What agenda for the review of TRIPS?: A sustainable development perspective

by David Vivas Eugui[1]

The objective of this informal note is to give non-governmental organizations (NGOs) an overview of the results of the Doha Ministerial of the World Trade Organization (WTO) and of negotiations and reviews currently underway in the Council for Trade-Related Aspects of Intellectual Property Rights (TRIPS Council) of the WTO. The note will also present some views on how North-South divisions over intellectual property rights could be bridged, and how some of civil society's concerns could be addressed. In addition, this note will analyze the need to rebalance the Agreement on Trade-Related Intellectual Property Rights (TRIPS Agreement), the content of the Doha Mandates and finally some new inter-linkages that arise with the World Intellectual Property Organization (WIPO).

The need to rebalance the TRIPS Agreement

The TRIPS Agreement has become one of the WTO Agreements most heavily criticized by people from developing countries, civil society and consumers. Existing international rules on intellectual property rights (IPRs), as currently written, are imbalanced and tend to undermine progress towards sustainable development. Overly strong intellectual property rights, together with extended scope and duration of protection of these rights, are shifting control over information from consumers to producers and from Southern to Northern countries, and therefore consolidating control over one of the most important resources - knowledge. This shift in balance has the potential to negatively affect access and transfer of technologies, incentives to individual and community innovators, access to drugs, development options and the implementation of international environmental agreements, such as the Convention on Biological Diversity (CBD).

In some cases, IPRs are just protecting economic investments and activities with very small or non-existing intellectual added-value, opening the door for legal monopolies in the field of biotechnology and information technologies. IPRs in many cases are not counter-balanced with adequate competition policy and laws to address predatory actions in certain markets. This situation has raised citizens' concerns in both

[1] Senior Attorney at the Center for International Environmental Law.

the developed and developing world and is deeply limiting the scope of the public domain.

We believe that, if established at an appropriate level, IPRs can and should promote innovation, encourage investment and balance the public interest in access to new products, processes and other forms of innovation with the need to reward all types of innovators for their creativity.

The TRIPS Agreement and the Doha Ministerial Declaration

As a consequence of the concern that the TRIPS Agreement places private rights over public concerns such as health, food security, development and environment, the WTO's Doha Ministerial Declaration opened the possibility of some initial steps towards rebalancing the TRIPS Agreement. These steps included the recognition of health concerns by trade Ministers within the TRIPS and Public Health Declaration, a set of immediate decisions and negotiations on implementations concerns, and mandated reviews of the relationship between the TRIPS Agreement and CBD as well as the protection of traditional knowledge.

The TRIPS Agreement and public health. The Declaration on the TRIPS Agreement and Public Health[2] is a key Ministerial text for developing countries. Although the declaration is mainly of a political nature, it achieved two important goals. First, the Health Declaration gives more space for flexible interpretations of the TRIPS Agreement in relation to health issues. This space for interpretation can help developing countries resist bilateral pressures by developed countries on behalf of their corporations, and thus reduces the risk of potential disputes linked to the TRIPS Agreement and the implementation of national health policies. Second, according to this declaration, "*least-developed country Members* ***will not be obliged****, with respect to pharmaceutical products, to implement or apply Sections 5 and 7 of Part II of the TRIPS Agreement or to enforce rights provided for under these Sections* ***until 1 January 2016***". This decision therefore allows developing and least developed countries to take the necessary steps for improving health conditions in their respective territories and to implement policies designed to create a national pharmaceutical sector that can respond to their health needs.

Two particular actions are in the agenda for developing countries and civil society in relation to the TRIPS Agreement and health.

- Need for full implementation of the Health Declaration. This would imply the provision of demand-driven capacity building programs to developing countries by the WTO, WIPO and developed countries, in order to find ways to enhance the flexibility given by this Declaration;
- Finding an expeditious solution for countries with insufficient manufacturing capacity in the pharmaceutical sector, so that they may effectively use compulsory licensing under the TRIPS Agreement, as provided by paragraph 6

[2] WT/MIN(01)/DEC/W/2 of the 14th of November 2001.

of the Health Declaration. In finding this solution, Article 30 of the TRIPS Agreement should be authoritatively interpreted in such a way that countries without manufacturing capacity can issue compulsory licensing to import medicines from any source. In this sense, countries with manufacturing capacity should be able to allow production and export of medicines under patent to countries needing those medicines. Also, quantitative restrictions on exports contained in Article 31(f) of the TRIPS Agreement should be removed.

Implementation issues. The text of the paragraph 12 of the Doha Ministerial Declaration[3] states:

"….we further adopt the Decision on Implementation-Related Issues and Concerns in document WT/MIN(01)/W/10 to address a number of implementation problems faced by Members. ***We agree that negotiations on outstanding implementation issues shall be an integral part of the Work Programme*** *we are establishing, and that agreements reached at an early stage in these negotiations shall be treated in accordance with the provisions of paragraph 47 below.* ***In this regard, we shall proceed as follows: (a) where we provide a specific negotiating mandate in this Declaration****, the relevant implementation issues* ***shall be addressed under that mandate****; (b)* ***the other outstanding implementation issues shall be addressed as a matter of priority by the relevant WTO bodies****, which shall report to the Trade Negotiations Committee, established under paragraph 46 below, by the end of 2002* ***for appropriate action****."* (boldface added).

Two immediate decisions were taken by Ministers at Doha in relation to implementation:

- Non initiation of non-violation complaints until recommendations on the modalities and scope are presented to the fifth Ministerial. This decision will permit all countries interested in a deeper debate on the feasibility of having non-violation in the TRIPS Agreement to present their views. Members should thus reconsider the application of non-violation complaints to the TRIPS Agreement. We share the view of almost all WTO members that non-violation complaints "*may constrain members ability to introduce new and perhaps vital and social, economic development, health, environmental, and cultural measures*" (proposal from Cuba, Dominican Republic, Egypt, Indonesia, Malaysia and Pakistan). The moratorium contained in Article 64 of the TRIPS Agreement on non-violation complaints should be extended indefinitely.
- The TRIPS Council must put in place a mechanism to monitor and ensure that developed countries fully implement their obligation to establish incentives for the transfer of technology to least developed countries. Developed countries should establish effective incentives and appropriate mechanisms for transferring technology to least developed countries in their own legislation. These incentives could include, among others, tax incentives to firms for

[3] WT/MIN/(01)/DEC/W1 of the 14th of November 2001.

improving technology transfer, educational and capacity building programs, and scientific cooperation agreements.

In general terms all issues contained in the Decision on Implementation-related issues[4] and in the Outstanding List of Implementation Issues[5] imply opportunities for developing countries. In principle, developing countries affirm that all implementation issues listed in the implementations texts are under negotiation and are a full part of the work programme. The main opportunity the list of implementation issues brings to developing countries is the possibility of a focused negotiation without taking the risk of including many issues that could reduce even more the little space for flexibility in the TRIPS Agreement.

The list of implementation issues under negotiation includes the following:

- The examination of the scope and modalities for the application of non-violation complaints. (Article 64.2 of the TRIPS Agreement).
- Implementation of mechanisms for enforcement and monitoring developed countries obligations to provide incentives to their enterprises in order to generate technology transfer (Article 66.2).
- Negotiations to extend protection of geographical indications to other products than wines and spirits. (According to Articles 23 and 24 of the TRIPS Agreement).
- Interim suspension of granting patents that do not fulfill Article 15 of the CBD.
- No implementation of the provisions of Article 27.3b until five years pass from its review.
- Extension of the implementation period of the TRIPS Agreement for least developed countries.
- Operationalization of Articles 7 and 8 of the TRIPS Agreement.
- Clarification that no patents should be granted on life.
- Amendment of Article 27.3b in the light of the principles of the CBD and the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA), as well as several issues linked to farmers rights, food security, patentability of life, and the protection of indigenous innovations. There are two options in relation to this point. Both options are still under brackets, which means that it has not yet been decided if they are part of the implementation list.

<u>The relationship between the CBD and the TRIPS Agreement.</u>

Paragraph 19 of the Doha Ministerial Declaration instructs the TRIPS Council to pursue its work programme under Article 27.3b, Article 71.1, and paragraph 12 of the Ministerial Declaration "*to examine, inter alia, the relationship with the Convention of Biological Diversity and the protection of traditional knowledge…*".

[4] WT/MIN(01)/DEC/W/10 of the 14th of November 2001.
[5] Job(01)/152/Rev.1 of 27 of October.

There are several areas where actual and potential conflicts can occur between the TRIPS Agreement and the CBD. These conflicts occur mainly as a consequence of the lack of recognition of CBD principles into the TRIPS Agreement. Conflicts can also occur in the practical implementation phase of both agreements. The most important areas of actual or potential conflict are the following:

- The TRIPS Agreement allows private rights to be granted over genetic resources that are subject to sovereign rights. As such, it is in practice subordinating public rights over genetic resources, recognized in the CBD, to the grant of private rights such as patents under the TRIPS Agreement. Instead, the TRIPS Agreement should explicitly recognize the public international law principle of State sovereignty over natural resources as reflected in the UN Charter;

- Article 27 of the TRIPS Agreement disregards the fact that genetic material or traditional knowledge can be used in an inventive process or be incorporated in an invention without prior informed consent and benefit sharing. In this sense, the TRIPS Agreement allows the granting of patents regardless of whether a particular invention uses or incorporates legally or illegally accessed (i.e. accessed without prior informed consent and benefit sharing) genetic material or associated traditional knowledge. National access laws are not sufficient enough to prevent situations where the genetic material has been illegally accessed or used without authorization in an inventive process or incorporated into an invention out of the national jurisdiction. Hence, Article 27.3b) of the TRIPS Agreement has to be amended to require prior informed consent and the existence of fair and equitable benefit sharing agreements.

- Mechanisms to mandate the inclusion of prior informed consent and warranting benefit sharing are fundamental to achieve a cost-effective solution to illegal access of genetic resources and traditional knowledge. The disclosure of the origin of the genetic material and associated traditional knowledge will avoid initiation of expensive and numerous judicial actions to revoke patents that use or incorporate illegally acquired genetic material or associated traditional knowledge. This type of solution will not be more burdensome than any other regular requirement[6] or the ordinary disclosure of an invention. In a normal patent examination, a clear and sufficient disclosure of an invention can in many cases include the origin of the genetic resources as to permit a person skilled in the art to reproduce the invention[7]. The disclosure of the origin has even been

[6] Similar procedures exist in the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the purposes of the patent procedures (See Article 3). The Budapest Treaty is an Agreement subscribe under the auspices of WIPO. This type of procedure is only applicable to the biotechnology field. In this particular case, the voluntary deposit of microorganisms that accompanies the disclosure of the invention (which implies the existence special physical facilities) has never been considered as burdensome by WIPO members. There are also cases in national legislation where presentation of information on whether the invention has been produced under a governmental contract is requested.

[7] Especially in cases of endemic resources.

recently encouraged[8] by the Bonn guidelines of the CBD. This type of mechanisms should be included in Article 27.3b and 29 of the TRIPS Agreement.

- Article 27 of the TRIPS Agreement allows for the filing of patent applications over "inventions" that imply biological discoveries and genetic materials in their "*natural state*". Cases of patent applications and specific claims over biological discoveries and naturally occurring genetic resources together with associated traditional knowledge (both covered and protected by CBD) have been presented in many countries. Among these cases we can identify the neem tree and the ayahuasca. This situation has not only generated public condemnation but also a perception that IPRs are being used to circumvent CBD obligations. A clear understanding that patents cannot be granted over naturally occurring genetic resources should be included in the TRIPS Agreement.

The protection of traditional knowledge. Traditional knowledge tends to be characterized among others by the following features:

- It is subject to continuous evolution and generational improvement,
- It is orientated to practical solutions and survival,
- It has not been subjected to "Western" scientific methods,
- It is held by collective or individual subjects depending on the case,
- It has an intimate relationship with the habitat and the environment,
- In many cases, it lacks material incorporation,
- Oral transmission is the prevalent preservation rule (in some cases codified and documented),
- It combines religious, moral, cultural, political and commercial values,
- It is a private right, held either collectively or individually depending on the prevalent customary norm or law,
- It tends to generate informal products.

These special features make traditional knowledge a very particular object of protection, especially considering that existing IPRs regimes are limited and do not cover all aspects of traditional knowledge. Therefore, traditional knowledge is best protected by an effective *sui generis* system capable of consolidating and reflecting its particular nature, which takes into account the rights and interests of the indigenous and local communities that developed traditional knowledge. Alternatives for finding and implementing an effective national, regional or international *sui generis* system must be kept open.

A possible way of rebalancing the TRIPS Agreement and protecting all types of innovation systems would be an amendment of Article 27.3(b) of the TRIPS Agreement

[8] Annex C. " *the conference of the Parties,*

1. Invites Parties and governments to encourage the disclosure of the country of the origin of genetic resources in applications of intellectual property rights, where the subject matter of the application concerns or makes use of genetic resources in its development, as a possible contribution to tracking compliance with prior informed consent and the mutually agreed terms on which access to those resources was granted".

requiring WTO members to provide for the protection of traditional knowledge and folklore by an effective *sui generis* system. Such a protection should be designed in light of the CBD, the ITPGRFA, and existing regional and national regulatory frameworks.

New issues arising under the review of Article 71.1. There is no definition of what is considered to be a "new development". This wording comes from Article 71.1 of TRIPS and in principle both developing countries and developed countries can define from their own perspective what is considered to be new developments. The Ministerial Declaration instructs the TRIPS Council "*to examine…., inter alia, …..any new development raised by Members pursuant to Article 71.1*." This implies that only new developments presented by members will be taken into account. Issues raised by members pursuant to Article 71.1 include the protection of traditional knowledge and intellectual property issues related to e-commerce and the Internet.

A possible list of issues of potential interest for developing countries and civil society under Article 71.1 could include among others:

- Developing Article 40 of the TRIPS Agreement so as to establish guidelines on the relation between competition policy and intellectual property rights,
- Revisiting technology transfer obligations under Article 66.2 for the inclusion of developing countries,
- Reviewing excessive rights given to patent holders,
- Reviewing and deepening special and differential treatment clauses in TRIPS.

Interlinkages between the work in the TRIPS Council and in WIPO:

There are several areas where the work of the WTO's TRIPS Council and WIPO can interlink. Before the TRIPS Agreement entered into force, most of intellectual property negotiations and discussions were held at WIPO. This situation changed when the TRIPS Agreement established a new set of minimum standards on diverse areas of the intellectual property system, which generated a range of linkages with the scope and content of several WIPO Agreements.

Linkages arise from a number of sources, including a common object (intellectual property rights), incorporation of the content of several WIPO Agreements into the TRIPS Agreement (Paris, Bern and Rome, Washington, etc.), forum shopping by some WTO and WIPO members in light of national interests, availability of a dispute settlement mechanisms, and the need for coordinated technical assistance to support the interests of developing countries.

Currently, there are two areas of interlinkages between TRIPS and WIPO work where active NGOs should look with some attention. These are the following:

Work on patents. The TRIPS Council has begun to review the full text of the TRIPS Agreement under Article 71.1. This review includes all sections of the TRIPS

Agreements including the section on Patents (section 5). WIPO, in turn, is advancing toward a new patent agenda. This agenda would include, among other activities, promoting activities for the ratification of the Patent Law Treaty (PLT), promotion of the concept and need for a universal patent, negotiations of the Substantive Patent Law Treaty (SPLT) and the reform of the Patent Cooperation Treaty (PCT). In both cases, various questions arise: do flexibility for interpretation and spaces for national or regional patent procedures need to be preserved? Have negotiations and discussions developed an appropriate balance between private and public rights? Is civil society ready for a process leading towards a universal patent or detailed harmonization of patent law?

Work on genetic resources and the protection of traditional knowledge. As was mentioned, the TRIPS Council has yet to finish reviewing Article 27.3b. According to the Doha Ministerial Declaration, the TRIPS Council is instructed "*in pursuing its work programme under Article 27.3b)* (…) and 71.1 *to examine the relation between CBD and TRIPS and the protection of traditional knowledge*" (TK). In the other hand, WIPO is deepening its work in the Intergovernmental Committee on genetic resources, traditional knowledge and folklore (IGCGRTKF) in relation to contractual clauses in access contracts, searches for prior art and possible *sui generis* options for the protection of TK. Some questions for civil society could include: What should be the content of a protection for traditional knowledge? Does civil society want a unique *sui generis* system to protect traditional knowledge or flexibility for different *sui generis* systems based on national approaches?

Concluding remarks

New Doha Ministerial texts include a set of mandates to negotiate and review a wide variety of issues. These negotiations and reviews are fundamental to rebalance the TRIPS Agreement under a sustainable development perspective. Steps like the Health Declaration have shown that public interests can and should be acknowledged in the TRIPS context.

Many of the issues under negotiation or review are common concerns to developing and developed country citizens. Measures to facilitate access to medicines, recognition of the principles of the CBD, protection of all types of innovative schemes, and competition policies and law inside the intellectual property regime are shared objectives of civil society in both developing and developed world.