CENTER FOR INTERNATIONAL ENVIRONMENTAL LAW

ISSUES LINKED TO THE CONVENTION ON BIOLOGICAL DIVERSITY IN THE WTO NEGOTIATIONS: IMPLEMENTING DOHA MANDATES

BY

DAVID VIVAS EUGUI[1]

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The Author

David Vivas Eugui
Senior Attorney
CIEL, Europe
BP 21, 160a Route de Florissant
1231 Conches, Geneva, Switzerland
Phone: 41 22 789 0738
Fax: 41 22 789 0500
Email: dvivas@ciel.org

I. Introduction

The relation between the objectives of the Convention on Biological Diversity (CBD) and the TRIPS Agreement has been subject to continuous debate in the World Trade Organization (WTO), especially in the TRIPS Council and in the Committee on Trade and Environment (CTE). The core of these discussions has been focused on the lack of recognition of the objectives of the CBD by some members as well as and the need to incorporate those objectives into the text of the TRIPS Agreement. The main vehicles used by developing countries in the pre-Doha negotiations phase for promoting the recognition and the incorporation of the CBD objectives were the review of Article 27.3(b) in the TRIPS Council and the work undertaken in the CTE of the WTO.

Many developing countries worked hard during the Doha Ministerial process to introduce new mandates on the relation between the CBD and the TRIPS Agreement. This situation has been reflected in the recently approved Doha Ministerial Declaration by several direct and indirect references to the relation between the CBD and the TRIPS Agreement. These references clearly show a strong political will by WTO Ministers to find synergies between the objectives of the CBD and the content of the TRIPS Agreement. The references can be found in the List of Outstanding Implementation Issues[1], and in two sections of the Doha Ministerial Declaration text [2].

The CBD is an international agreement for the conservation of biological diversity. The Convention's objectives, in addition to the conservation of biological diversity, include the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the use of genetic resources, including through appropriate access to genetic resources, and transfer of relevant technologies[3]. These objectives are of crucial importance for developing countries. Sustainable use of biodiversity is accomplished through the establishment of a system of access that permits control and preservation of the genetic resources, measurement of the environmental impact, the existence of prior and informed consent by the host government and traditional communities, and the fair and equitable sharing of benefits deriving from genetic resources.

The implementation of the TRIPS Agreement is affecting the fulfillment of the CBD in different areas. This includes: the placement of private rights over public rights; the recognition of patents and other intellectual property rights (IPRs) using genetic resources and traditional knowledge without prior informed consent and benefit sharing; the lack of acknowledgment over alternative innovation systems that could be useful to society; tendency to promote monoculture; reduction of plant diversity; incremental use of genetically modified organisms; etc.

This document analyses the content of TRIPS and CBD- related mandates contained in the Ministerial texts approved at Doha. It aims to provide developing countries with suggestions for common action in the relevant WTO bodies. While most of the attention is being given to the Ministerial Declaration, issues of crucial importance for developing countries can be found in the Decision on Implementation Related Issues and Concerns[4], and in the Compilation of Outstanding Implementation Issues.

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1 JOB(01)/152/Rev.1 of the 27th of October 2001. Tirets 15, 95 and African Proposal.

2 See WTO document WT/MIN(01)/DEC/1 of the 20th of November 2001. Paragraph 12.

3 See Article 1 of the CBD, 1992.

4 See WTO document WT/MIN(01)/DEC/17 of the 20th of November, 2001.

To assist developing countries choosing the most promising strategies, this brief identifies valuable interpretative links and suggests a list of items for a common review agenda.

II. Implementation issues and the CBD: The need to consolidate the negotiation mandates

II. 1 The treatment of implementation issues in paragraph 12 of the Ministerial Declaration

The implementation issues were among the most urgent demands of developing countries during the negotiations of the Doha Ministerial. Implementation concerns consist of those issues presented by developing countries to rebalance existing WTO Agreements and to resolve problems of putting existing agreements into practice. The structure of the current implementation texts is divided between immediate actions (contained in the Decision on Implementation Issues) and future actions (contained in the Compilation of Outstanding Implementation Issues raised by Members).

The text on immediate actions includes those decisions that can be implemented without delay and that do not require any changes in existing WTO Agreements. However, this part of the implementation text does not contain any references to biodiversity issues. The implementation text that refers to future actions includes issues that could be addressed only through new negotiations. This later text, which is contained in the Compilation of Outstanding Implementation Issues, includes direct references to issues related to biodiversity.

Box 1

Paragraph 12 of the Ministerial Declaration.

According, to paragraph 12 of the Ministerial Declaration, Members…"***agree that negotiations on outstanding implementations shall be an integral part of the Work Programme***"*… 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."*

Paragraph 12 states clearly that Outstanding Implementation Issues are under negotiations and are a full part of the work programme. This interpretation is fully supported by:

- The above-mentioned negotiation division between implementation issues for immediate action and for future action;
- The declaration of members agreeing on negotiations on outstanding implementation issues; and
- The fact that the results of these negotiations shall be reported to the Trade Negotiations Committee, which is the main institutional body that will carry out this negotiations during the Doha round.

Many countries do not agree with this interpretation and will make efforts to undermine the development and amendment of the WTO agreements in light of the implementation concerns. For this reason, consolidation of the negotiation status of the Compilation of Outstanding Implementation Issues should be addressed by developing countries in the

TRIPS Council meetings in order to secure any gains that have been obtained in the Doha Ministerial process. Brazil and India have already been partially successful in making this clear in their declarations. Nevertheless, it could be wise for developing countries to prepare a joint Declaration by developing countries to respond to potential individual developed country statements by some developed countries that might be designed to create uncertainty and to reduce the value of paragraph 12 of the Ministerial Declaration and the Compilation of Outstanding Implementation Issues.

The Compilation of Outstanding Implementation Issues contains two tirets and one proposal related to biodiversity issues and the TRIPS Agreement. This compilation is not a finalized text and it was furthermore not approved directly by the Ministers in Doha[5]. Its political value comes from references contained in paragraph 12 of the Ministerial text and in footnote 2 of the Decision on Implementation Related Issues and Concerns. The tirets and the proposal related to biodiversity issues and the TRIPS Agreement comprise the following:

II.2 Tiret 15

Box 2

Text of Tiret 15

"A clear understanding in the interim that patents inconsistent with Article 15 of the CBD shall not be granted".

Article 15 develops one of the main objectives of the CBD: "*to achieve fair and equitable sharing of the benefits arising out of the utilization of genetic resources*"[6]. It contains several basic principles concerning access to genetic resources, including:

- Recognition of sovereign rights over genetic resources;
- Access based on prior informed consent;
- Access and benefit sharing based on mutually agreed terms;
- Joint research activities over genetic resources.

Tiret 15 is designed to establish an interim "*consistency examination*" in the patent procedure. This "*consistency examination*" becomes in practice, a new requirement to patentability,[7] and not an exception to patentability. The reason is that if an invention has fulfilled the traditional criteria for patentability as set out in Article 27.1 of TRIPS (novelty, inventive step and industrial application) and has followed the principles of Article 15 of the CBD, a patent must be granted. An exception to patentability would be an absolute prohibition of granting patents, even if all requirements were met. This type of requirement is not directly related to the traditional patentability requirements but to the fulfillment of an obligation derived from a Multilateral Environmental Agreement (MEA).

5 The main reason is that this text is a job document.

6 See Article 1 of the CBD.

7 The creation of a new requirement of patentability is not something that is going to be easily acceptable by some developed countries. In many developed countries, the latest legislative changes are taking a completely opposite direction by reducing and softening the traditional patentability criteria, especially in the case of the inventive step and in the case of the industrial application.

The mandate included in tiret 15 calls for the establishment of an interim measure to avoid "misappropriation"[8] of genetic resources through patents while a definitive solution is found concerning the relation between the CBD and the TRIPS Agreement. The term "interim" in tiret 15 refers the period between the finalization of negotiations on implementation issues and the finalization of the reviews and focus amendments of the TRIPS agreement in light of the CBD [9]. This is not a definitive solution to the lack of recognition and incorporation of CBD objectives in the TRIPS. Nevertheless, the establishment of such a measure could put pressure on countries objecting to the recognition and incorporation of the CBD principles into the TRIPS Agreement and to finding appropriate arrangements.

A possible interim measure could take two forms:

- A Decision by WTO members to declare a moratorium on Disputes concerning the relation between CBD and TRIPS;
- The introduction of a transitional arrangement in the TRIPS text developing the content of tiret 15. This second option could be very useful in case a focus amendment to the TRIPS text is not obtained as a consequence of the reviews of Article 27.3(b) and 71.1.

From a legal point of view, the mandate of tiret 15 is the only clear negotiation mandate in relation to biodiversity issues. Other references to biodiversity issues in the compilation of outstanding issues were not approved by all members. Therefore, tiret 15 could potentially constitute the most suitable point of departure for actions oriented to obtain recognition and incorporation of the CBD objectives in the TRIPS Agreement.

II.3 Tiret 95

Box 3

Text of tiret 95

Tiret 95 first version.

[Article 27.3(b) ***to be amended*** *in light of the provisions of the Convention on Biological Diversity and the International Undertaking. Also, clarify artificial distinctions between biological and microbiological organisms and processes; ensure the continuation of the traditional farming practices including the right to save, to exchange and save seeds, and to sell their harvest; and to prevent anti-competitive practices which will threaten food security and sovereignty of people in developing countries, as permitted by Article 31 of the TRIPS Agreement.]*

Tiret 95, second version.
[Article 27.3(b) ***should be amended*** *to take into account the Convention on Biological Diversity and the International Undertaking on Plant Genetic Resources. The amendments should clarify and satisfactorily resolve the analytical distinctions between biological and microbiological organisms and processes; that all living organisms and their parts cannot be patented; and those natural processes that produce living organisms should not be patentable. The amendments should ensure the protection of innovations, of indigenous and local farming communities the continuation of traditional farming processes including the right to use, exchange and save seeds, and promote food security.]*

8 Technically, patents do not establish full property rights but give exclusive rights over an invention during a limited period of time.

9 Read it jointly with tiret 95 under brackets.

Both versions of tiret 95 call for the amendment of Article 27.3(b) in the light of the provisions of the CBD and the International Undertaking. The first version was designed to establish a clear obligation to amend Article 27.3(b), while the second is just a statement that Article 27.3(b) *should* be amended. The first version puts more emphasis on the clarifying of the exceptions to patentability and the limitations to the plant variety protection, while the second focuses more on some of the issues related to protection of traditional knowledge.

A political decision on the status of these proposals was not reached in Doha and both texts are still under brackets. Nevertheless, this does not mean that the discussion of its inclusion has finished. On the contrary, discussions on the content of the compilation of the outstanding list of issues are still open.

Developing countries should make clear that the debate on implementation issues has not finished. The fact that discussions were not closed should be taken as an opportunity to insist in the continuation of the implementation discussions as a full part of the WTO work programme.

II.4 Proposal from least-developed countries

Box 4

Proposal of least-developed countries

"*The General Council agrees that the* ***review process*** *should clarify that living organisms, including plants, animals, and parts of plants and animals, including gene sequences, and biological and other natural processes for the production of plants, animals and their parts,* ***shall not be granted patents***".

The objective of this proposal was to make a general and mandatory exception to patentability of life. The proposal calls for an agreement of the General Council because of the review process in the TRIPS Council. This proposal is not designed to tackle biodiversity issues. Nevertheless, an exception to the patentability of life could have positive effects in reducing the probability of misappropriation of genetic resources.

The text of this proposal is not under brackets, but the title identifies it as a proposal. This suggests that there was no final agreement on this proposal. As in the preceding tiret, discussions are not closed. In fact they can theoretically continue if developing countries consider this an issue of importance.

Developing countries should promote the continuation of discussions on tiret 95 and the proposal of least-developed countries in the next TRIPS Council. It could be beneficial for developing countries in the medium term to sustain alive all potential mandates (agreed or not) that could favour the incorporation of CBD objectives in the TRIPS Agreement and reduce the opportunities for misappropriation of genetic resources.

III. Mandated reviews of the TRIPS Agreement: Preparing the terrain for future amendments

III. 1. Strategic considerations on paragraph 19 of the Ministerial Declaration

The only relevant Ministerial text that addresses in relation to the reviews of the TRIPS Agreement is the Ministerial Declaration. Paragraph 19 of the Ministerial Declaration specifically deals with existing reviews under Article 27.3(b) and Article 71.1 of the TRIPS Agreement.

Box 5

Text of paragraph 19 of the Ministerial Declaration

We instruct the TRIPS Council, in pursuing its work program included under the review of Article 27.3(b), the review of the implementation of the TRIPS Agreement under Article 71.1 and the work foreseen pursuant to paragraph 12 of this Declaration, ***to examine****, inter alia,* ***the relationship between the TRIPS Agreement and the Convention on Biological Diversity, the protection of traditional knowledge and folklore****, and other relevant new developments raised by Members pursuant to Article 71.1. In undertaking this work, the TRIPS Council shall be guided by the objectives set out in Articles 7 and 8 of the TRIPS Agreement and shall take fully into account the development dimension.*

The text of paragraph 19 clearly foresees that the TRIPS Council will pursue the review under Article 27.3(b) and Article 71.1 separately. In this context the TRIPS council must examine the relationship between TRIPS and the CBD when the issues come up during 27.3(b) review or during 71.1 review or any of the work foreseen under paragraph 12. This implies that this relationship should be examined fully and comprehensively. In case the new developments arising under 71.1 are also relevant for the discussion under 27.3(b) then they should also be examined under that context.

So far, the review of Article 27.3(b) has been oriented towards an analysis of exceptions to patentability, biodiversity issues, *sui generis* options for the protection of plant varieties and other issues of interest to developing countries and civil society in general. This review has been the *main point of* entrance for proposals that seek to rebalance the TRIPS agreement and to introduce, agricultural, social and environmental concerns. By merging the different reviews, the Ministerial Declaration has placed the incorporation of "new developments", such as those pursuant to Article 71.1[10] onto the same legal level as discussions under Article 27.3(b).

Paragraph 19 calls for the examination of the relation between the CBD and the TRIPS Agreement. This examination mandate is neutral in nature. Nevertheless, it is positive to have an express mention of the CBD in a Ministerial text. Such a clear mention can open the door for deeper discussions on possible inconsistencies and the different objectives of both agreements.

[10] Article 71.1 contains a full review of the TRIPS Agreement as a whole. An unfocused review of the TRIPS Agreement can bring new issues and new intellectual property standards into the negotiations (for which most of developing countries are not ready), including patents on business procedures, patents on life, extended plant variety protection, *sui generis* protection of databases, renewed standards on enforcement, etc. This may considerably weaken developing countries' opportunities in rebalancing the TRIPS Agreement, particularly in areas of interest to developing countries, like the inclusion of the requirement for disclosing the origin of the genetic resourses, and the protection of traditional knowledge, the non-patentability of life, flexible *sui generis* systems for protecting plant varieties and, recognition of farmers rights., etc.

In paragraph 19, there is also an express mention of examining the protection of traditional knowledge (TK) and folklore. TK usually means an intellectual value added over the genetic and biological resources existing in nature. The use of the term "protection" helps to qualify TK and folklore as "TRIPS Agreement plus" issues. This is positive, as it might facilitate future inclusion of TK as a possible negotiating item.

III.2. Various Approaches to the relation between the CBD and the TRIPS Agreement and on the protection of TK in the TRIPS Council

Clarifying the relation between the CBD, the TRIPS Agreement, and the Protection of TK, requires a recalling of the main approaches used by WTO Members in the TRIPS Council. These approaches will shape future discussions and will have influence in the creation of country coalitions in favour or against the incorporation of CBD objectives into the TRIPS Agreement. There are various specific approaches on these two qualified elements of the mandated reviews, including the following:

III.2.1. Main Approaches on the relation of the CBD and the TRIPS agreement

The relation of the CBD and TRIPS has been approached in the TRIPS Council in three different ways. These are the following:

1. Conflicting relation: 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:

- TRIPS allows private rights to be granted over genetic resources that are subject to sovereign rights. As such, this 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 a genetic material or a traditional knowledge can be used in an inventive process or 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 genetic material or associated traditional knowledge (meaning without prior informed consent and benefit sharing). National access laws are not 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 outside of the national jurisdiction. Hence, Article 27.3 b) 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 the warranting of 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

illegal acquired genetic material or associated traditional knowledge. This type of solution will not be more burdensome than any other regular requirement 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 so as to permit a person skilled in the art to reproduce the invention. Even the disclosure of the origin has been recently encouraged by the Bonn guidelines on Access and Benefit Sharing of the CBD. This type of mechanisms should be included in Article 27.3(b) 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 Ayahuasca cases. This situation has not only generated public condemnation but also a perception that intellectual property rights 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.

2. No conflict but a need to review the TRIPS accordingly to the CBD: This view considers that although the objectives and subject matter of both agreements are quite different, they are not conflictive. According to this view, conflict can potentially occur when the TRIPS Agreement is implemented nationally without taking into account the objectives and obligations under the CBD. In this sense, objectives of both agreements and their national implementation need to be reconciled. Intellectual property rights (private rights) should not prevail or undermine sovereign rights (public rights). In practice both the conflicting and the non- conflicting approaches seek the amendment of the TRIPS Agreement in light of the CBD.

3. No relation between CBD and the TRIPS Agreement: This opinion considers that the TRIPS Agreement and the CBD have different objectives, subject matters, and distinct enforcement mechanisms. They do not have areas of conflict, just different spheres of application and unrelated provisions. This view supports the notion which considers that private contracts on access are enough to warrantee the objectives of the CBD. Intellectual property (IP) is not a vehicle for enforcing the CBD. Under this view the TRIPS Agreement should remain untouched.

III.2.2 The traditional knowledge and main approaches on its protection.

The term traditional knowledge informally includes all type of "knowledge, innovations, practices of local and indigenous communities". Traditional knowledge has historically been the predominant way of innovation in all human cultures. It has been fully recognized that the indigenous and local communities efforts to protect and enhance biological diversity throughout time, has allowed the further development (industrialization and commercialization) of new crops, nutrients, dyes and colorants, natural medicines, perfumes, textiles, cosmetic and other products that have been extensively used by humankind as a whole, and disseminated among different cultures.

Indigenous and local communities have received very little recognition or compensation, in actual terms, for these contributions and their intellectual efforts in this respect. International

mechanisms for promoting and preserving this type of innovation process have not been fully agreed or implemented. These facts represent some of the reasons why it is now deemed necessary to protect the traditional knowledge, innovations and practices. Nonetheless, particular factors such as culture, religion, spirituality and communal identity have also contributed to reaffirm the need for a special solution.

Traditional knowledge tends to be characterized, in addition to 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 collectively or individually, subjects depending on the case, and
- In intimate relation with the habitat and the environment,
- In many cases, it lacks of 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, (again, held either collectively or individually) depending on the prevalent customary norm or law,
- It tends to generate informal products such as handicrafts.

These features have made traditional knowledge a very special subject of study. Existing approaches that mostly deal primarily with economic aspects of intangibles (IPRs) will not be the most suitable or sufficient for protecting and promoting the use of such knowledge.

The protection of TK has been approached by WTO members in the TRIPS Council in three different ways:

1. Need to protect traditional knowledge through a *sui generis* system: This approach considers that TK has its own particular features and that a special system of protection should consequently be created to cover them. The systems of existing IP protection were not designed to protect TK. There are knowledge, innovations and practices that cannot be protected by existing IP structures. They were mostly design to respond to the needs of the industrial and modern societies. According to this approach, *sui generis* system(s) to protect TK should be designed from a bottom-up approach and become part of the multilateral framework in the near future.

There is not a consensus understanding on what should constitute the content of a *sui generis* system. Nevertheless, many biodiversity rich countries consider that the main benefits of *sui generis* systems is the possibility of having a special (of its own kind) system that could be flexible and open enough as to include national features and community needs.

2. Protection of traditional knowledge should be tested and implemented at a national level: This approach considers that it might not be possible or even desirable to have a multilateral system for the protection of TK. However, experience is lacking at a national level and time is needed to generate more mature and precise ideas. Some of the defendants of this approach affirm that national systems of TK for the protection of TK must be consistent with the TRIPS Agreement.

3. Traditional knowledge can be protected through existing intellectual property figures: This view supports the notion that the current IP system is enough to protect traditional knowledge that fulfils the protection criteria and that there is no need to adapt or create special rules for TK holders. According to this view, there is just a lack of enough knowledge on the benefits and use of the IP system.

III.3. Suggestion for common actions

At this stage, the mandated reviews are the only vehicles available to promote comprehensive changes in the TRIPS text. The only way that existing mandated reviews could be changed into negotiation reviews in the next Ministerial Conference will be to create a common agenda for biodiversity rich countries in the TRIPS council on CBD and TK issues. Without a common agenda, it will be very difficult to prepare joint proposals by developing countries in the TRIPS Council.

IV. Toward a common agenda on CBD issues

The need for the development of a common agenda on CBD issues will be essential for achieving success in amending the TRIPS Agreement in light of the objectives and principles of the CBD. . Several reasons support this approach. First of all, developing countries cannot, due to the differences in bargaining power, sustain more than two or three issues in the review processes. Second, the biodiversity discussions are not only limited to the review, but the work program also includes mandates related to biodiversity under the implementation negotiations and under the CTE. Third, the CBD is not a panacea. Many countries that are not Parties to it have also negotiated its content. Therefore, CBD obligations have already been balanced by concerns of these countries over IP, especially in the biotechnology field. A possible list of issues for a common review agenda dealing with the relation between of the CBD and the TRIPS Agreement and the Protection of Traditional Knowledge could include:

***Recognition of sovereignty rights over genetic resources*:** The main principle of the CBD is the sovereign right of the Parties to exploit their own genetic resources pursuant to their own environmental policies [11]. One of the main problems that biodiversity rich countries have faced in the discussions under the 27.3(b) review is that some countries[12] do not recognize sovereign rights[13] over genetic resources. Developing countries should seek an express recognition in the TRIPS Agreement that any private use of genetic resources, including intellectual property, should be subject to sovereign rights and that the authority to determine access to genetic resources should rest on national governments [14].

Incorporation of principles of prior informed consent (PIC) and benefit sharing (BS) in the TRIPS. These two principles are the core of the CBD access regime. The PIC and the BS have been implemented nationally through national legislation and private access contracts. These principles need to be complemented with mechanisms that could warrant their existence before the grant of any IPR.

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[11] See Article 3 of the CBD.

[12] They tend to consider genetic resources as a common patrimony of humanity and therefore free for use.

[13] There is no definition of what is considered sovereign rights over genetic resources in the CBD, leaving the definition to the Parties.

[14] See Article 15 of the CBD.

Need for disclosure of the origins of genetic resources and TK in the patent description: This is one of the more controversial proposed mechanisms to warrant the existence of PIC and BS. The existence of such a mechanism would seek not only to enforce CBD principles but also to clarify the description of any biotechnology inventions. Similar procedures exist in the 'Budapest Treaty on the International Recognition of the Deposit of Microorganisms' for the purposes of the patent procedures. The Budapest Treaty is an agreement subscribed under the auspices of World Intellectual Property Organization (See Article 3).

Recognition of IPRs registration as a commercial use of genetic resources or TK: The CBD covers access and use of genetic resources for experimentation, commercial purposes and other uses. It is clear that the registration of IPRs has an obvious commercial objective. IPRs are filed with the purpose of obtaining temporal exclusive rights in the market place. Even if an IPR is not used commercially, the logic of its existence is to use it as an economic tool. Recognition of IP registration as a commercial activity may facilitate the establishment of a clear relation of incompatibility between the TRIPS and the CBD.

No patentability of substances and living organisms existing in nature: Making a clarification or even a mandatory extension of the exceptions to patentability in Article 27.3 of the TRIPS Agreement can reduce the possibility of misappropriation over genetic resources. Another possible way to reduce the scope of patentability could be to define what is considered an "invention" in Article 27.1 of the TRIPS Agreement. Such a definition should neither include discoveries, nor substances and organisms living in nature. This latter possibility, however, can also have some disadvantages by opening a definition exercise over the patentability criteria.

Recognition of flexibility in the TRIPS Agreement for establishing national enforcement measures to implement the CBD: Countries must have space to include measures in their national legal systems (including the IPR legislation) to implement CBD obligations. These measures could include open civil, administrative and criminal actions.

Insert an obligation to implement national legislation to protect the TK in accordance to Article 8(j) of the CBD: The obligation of Article 8j) of the CBD has not been fully implemented by all CBD Parties. Consequently, the Conference of the Parties (COP) of the CBD has created a Working Group on Article 8j) to closely follow its implementation. One possible first step toward the protection of TK, that can be initiated even prior to the discussion on the potential content of a multilateral *sui generis* system, is to incorporate CBD obligations to respect, preserve and maintain knowledge, innovations and practices of indigenous and local people[15] into the TRIPS Agreement.

Include a confidentiality obligation of TK and protection against unfair competition: The TRIPS Agreement contains mechanisms to protect undisclosed information (trade secrets) with commercial value[16] against unfair competition. This protection should be extended as to cover all TK preserved in secrecy with or without commercial value.

Identification of minimum standards for an effective sui generis system for the protection of TK: The IP system has proved to be insufficient and inadequate to protect TK. Exploring options that are more suitable to the titleholders and that respond to the special

15 See Article 8j) of the CBD.

16 See Article 39 of the TRIPS Agreement.

characteristics of TK could be a viable option for developing countries in the medium term. Almost all mechanisms used in national laws for protecting TK are in some way *sui generis*. Recently, many national laws have merged various principles and characteristics of the CBD, IPRs and human rights into their national systems for the protection of TK.

V. The work programme in the Committee on Trade and Environment and the CBD

The examination of the relation between TRIPS and CBD must be read together with the section on Trade and Environment of the Ministerial Declaration, and more specifically with paragraph 31 and 32.

V.1. Mandate of Paragraph 31

Box 6
Extracted text from paragraph 31

P. 31. Ministers "*agree to negotiations, without prejudging their outcome, on:*"

(i) "the relationship between existing WTO rules and specific trade obligations set out in multilateral environmental agreements (MEAs). The negotiations shall be limited in scope to the applicability of such existing WTO rules as among parties to the MEA in question. The negotiations shall not prejudice the WTO rights of any Member that is not a party to the MEA in question;"

In the CTE, several developing country members have promoted the need to transfer the objectives and principles of the CBD into the relevant WTO Agreements. In this context, several Members have presented their national experiences[17] on the joint implementation of CBD and WTO obligations. Nevertheless, the CTE has failed to reach any agreement on recommendations for future action. The current Ministerial texts called for negotiations on the relation between existing WTO and specific trade obligations contained in MEAs. It should be noted that the CBD is an MEA and could potentially be among the most important MEAs for developing countries. The relation between WTO Agreements and CBD in this case should not only be part of the discussions, but also part of the results of this negotiating exercise in the CTE.

V.2. Mandate of Paragraph 32

Box 7
Extracted text from paragraph 32

P.32. Ministers: "*instruct the Committee on Trade and Environment, in pursuing work on all items on its agenda within its current terms of reference, to give particular attention to:*"

*(ii) "**the relevant provisions of the Agreement on Trade-Related Aspects of Intellectual Property Rights**,"*

The Doha Ministerial Declaration instructs the CTE to give particular attention to the relevant provisions of the TRIPS Agreement. Several provisions of the TRIPS Agreement can have an impact on MEAs and more specifically on the CBD. As it has been mentioned, prevalence of private rights over public concerns and the lack of recognition of CBD objectives and principles by the TRIPS Agreement can generate potential inconsistencies. This situation can occur with regard to several provisions of the CBD. Relevant provisions of

[17] Some examples are Costa Rica, Colombia, Peru and India.

the TRIPS Agreement that could be identified by developing countries in the CTE might include the following:

- Article 1. Nature and scope of obligations
- Articles 7 and 8. Objectives and Principles
- Article 27.1, 27.2, 27.3. Patentable subject matter
- Article 29. Conditions on patent applicants
- Article 32. Revocation/Forfeiture
- Article 39. Protection of undisclosed information
- Article 41.2. Enforcement of IPRs, general obligations
- Article 71.1. Review and amendment

(A more precise explanation on the relation of these provisions with the CBD can be found in Annex I).

V.3 The advisory role of the CTE

The Doha Ministerial Declaration gives the CTE a new "advisory" role:

Box 8
Extracted text from paragraph 28

*P. 31. "Within its mandate by identifying any need for clarification in any WTO rules[18]. **The Committee would have the capacity to issue recommendations** with respect to future actions **including the desirability of negotiations**; at the same time the CTE could within its respective mandate, act as a forum to identify and debate environmental aspects of the negotiations, in order to help to achieve the objective of sustainable development".*

This advisory role of the CTE has a limited effect. Changes can be incorporated if there is consensus inside the CTE for recommending negotiations to the General Council or to the Ministerial Conference. Once the General Council receives the recommendations, this body has to analyze the desirability of new negotiations and only after that a new mandate for negotiations could be established. This procedure might be useful to include proposals in favour of introducing changes in the TRIPS Agreement. Nevertheless, this road could be extremely long for obtaining real results. It even requires analyzing the desirability of new negotiations, which would not be a popular step among WTO members interested in transferring CBD objectives and principles in the TRIPS Agrement.

[18] Idem note 1, paragraph 28.

VI. Coherence with other international organizations: Biodiversity as a horizontal intellectual property issue

The relationship between biodiversity issues and IPR has not been discussed exclusively in the WTO. These issues have also been discussed in the WIPO, FAO and the CBD.

WTO and WIPO. In general terms, there are many linkages between the WTO and WIPO. These include: a common object (IPRs), an incorporation of the content of several WIPO Agreements in the TRIPS Agreement (Paris, Bern and Rome, Washington, etc.), "forum shopping" by WTO and WIPO members in light of national interests, availability of a dispute settlement mechanisms, and the need for technical assistance.

On the other hand, WIPO and the WTO have different agreements that regulate IPRs. WIPO's agreements tend to regulate substantive[19] and the procedural[20] aspects of the protection of IPRs (mostly on acquisition and maintenance of IPRs). Alternatively, the WTO's TRIPS Agreement regulates commercial related aspects of IPRs (mostly availability, scope, use and enforcement of certain IPRs). This set of Agreements is fully independent [21] and is administrated under two different political frameworks.

Mandated negotiations and reviews in the TRIPS Council have the objective to examine, among other issues, the relation between CBD and the TRIPS Agreement and the protection of traditional knowledge. The work in IGCGRTKF is mainly oriented towards discussing the relation between genetic resources, TK and folklore in the IP system in general (without focusing correlation with any specific WIPO agreement).

All these interlinkages and differences in the scope can be used to the advantage of developing countries. Under this perspective, the TRIPS Council could be used as a way to incorporate CBD principles into the TRIPS Agreement together with some enforcement measures. Instead, WIPO could be a helpful forum for getting more specific regulation of genetic resources inside the IPR system and potential international *sui generis* protection for TK and Folklore.

WTO, CBD and FAO. The Doha Ministerial Declaration only mentions the CBD and the TRIPS Agreement. Currently biodiversity issues are covered by more than one international agreement. The recently approved International Treaty for Genetic Resources on Food and Agriculture (ITGRFA) of the Food and Agricultural Organization (FAO) and the CBD have created an international system for the conservation of biodiversity including non-agricultural and agricultural biodiversity. This system gives strength to biodiversity concerns and limits the ability of certain members of TRIPS Council to ignore these concerns.

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19 Paris Convention for the Protection of Industrial Property, Madrid Agreement for the Repression of False and Deceptive Indication of Source of Goods, Berne Convention for the Protection of Literary and Artistic Works, Rome Convention for the Protection of Performers, Producers of Phonograms and Broadcasting Organizations, WIPO Copyright Treaty, WIPO Performance and Phonograms Treaty.

20 Patent Cooperation Treaty, Patent Law Treaty, Trademark Law Treaty, The Hague Agreement for the International Deposit of Industrial Design, Lisbon Agreement for the Protection of Appellation of Origin.

21 Nevertheless, as it has been mentioned the TRIPS Agreement has incorporated made part of it several sections of the Paris Convention, the Berne Convention and the Washington Convention on Integrates Circuits.

In the context of the CBD, the COP has established two working groups with very precise mandates regarding fundamental aspects of access to genetic resources and TK. These groups are the Working Group on Article 8 (j)[22] and the Working Group on Access to Genetic Resources and Benefit-Sharing (WGABS)[23]. These two groups have advanced in their discussions and have presented many useful studies. The conclusions and recommendations of these two groups will be of great importance for achieving tangible results in the work programme of the WTO. One example is the recently approved Bonn Guidelines on Access and Benefit sharing by the Working Group II of the CBD. These guidelines clarify and develop most of the content of Article 15 of the CBD.

The CBD Secretariat can complement WTO's work with a great deal of experience in the actual CBD implementation at the national level. Nevertheless, inputs to the negotiation table will be limited if the CBD does not get a permanent status in the TRIPS Council.

VII. Conclusions

Finally, the conclusions can be presented as follows:

a) Negotiations on implementation constitute the most efficient way for generating changes in the TRIPS Agreement with respect to CBD. Tiret 15 of the outstanding list of issues is the strongest mandate for obtaining transitional measures while the TRIPS agreement is finally reviewed.

b) It is possible to link negotiations on implementation and the work on mandate reviews under articles 27.3b) and 71.1. due to similar coverage in certain points.

c) The relation between the CBD and the TRIPS Agreement and protection of TK should be included as specific items under this review independently if they fall under Article 27.3(b) or 71.1 or paragraph 12 of the Doha Ministerial Declaration. For a more comprehensive review of the TRIPS Agreement in light of the CBD and the ITGRFA, Article 71.1 seems to be a more suitable vehicle.

d) Gaps among the developing countries concerning different approaches to the CBD- and TRIPS relationship and the protection of TK need to be reduced in order to preserve possibilities to amend the TRIPS Agreement. The preparation of a list of common objectives, a common minimum agenda and clarity on the expected results coming from the review process can make developing countries tasks easier.

e) The Ministerial Declaration strengthens the advisory role of the Committee on Trade and Environment (CTE) but fails to provide sufficient authority to permit true reform of rules. In relation to the negotiations on the WTO rules and specific trade obligations in MEAs (and more precisely the CBD) a more circuitous road is created for obtaining changes in the relevant WTO Agreements.

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[22] COP IV of the CBD agreed, in decision IV/9, that an *ad hoc* open-ended intercessional working group be established to address the implementation of Article 8j) obligations and the related provisions of the Convention.

[23] The COP V, in its decision V/26, created the WGABS composed of representatives, including experts, nominated by Governments and regional economic integration organizations, with the mandate to develop guidelines and other approaches for submission to the Conference of the Parties and to assist parties and stakeholders in addressing issues relateded to access to genetic resources and benefit-sharing, taking into account *inter alia* the work of WIPO on intellectual property rights.

f) The CBD and The ITGRFA have achieved a new system for access to GR. Coherence with the work already undertaken in CBD and FAO will be necessary to avoid confusion and to obtain a horizontal recognition of the international system for access to GR in the WTO and WIPO.

g) Participation of the CBD and the FAO secretariat in the WTO and WIPO will provide useful experiences for the implementation of these agreements.

Annex I **Main TRIPS provisions that are related to the CBD.**	
Main TRIPS provisions	**Relation to the CBD.**
Article 1. Nature and scope of obligations	Article 1 of the TRIPS Agreement gives the right to WTO members to determine the appropriate method of implementing the provisions of the TRIPS Agreement within its own legal system and practices. CBD is obviously part of the legal system of more than 170 countries.
Article 7. Objectives	According to Article 7 of TRIPS "*protection and the enforcement of IPRs should contribute to (…) the transfer and dissemination of technology*". The CBD contains various clauses on technology transfer (T.T.). See CBD Articles 16, 17 and 18 of the CBD.
Article 8. Principles	According to Article 8 of TRIPS "*Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development*". For many countries to keep biodiversity in general or agricultural biodiversity is of vital important for the public interest and development. See preamble of the CBD and art. 6 of the CBD.
Article 27.1. Patentable subject matter	Article 27.1 contains an obligation to WTO Members to *have "patents (…) available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application"*. At the same time the Article set the criteria for patentability. In addition, "*patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced*". This Article has been used by several developed countries in the TRIPS Council to indicate that requirements to: a) ask patent applicants to prove prior informed consent and benefit sharing according to CBD principles or b) disclose the origin of the genetic resources or TK that are in violation of the TRIPS Agreement. Also, what could be considered invention, novelty, inventive step, and industrial application can have an important effect on the relation between the TRIPS Agreement and the CBD.
Article 27.2. Idem	Article 27.2 permits certain exceptions to patentability "*necessary to protect "ordre public" or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment*". This exception has been interpreted in a very limited way by jurisprudence. Nevertheless it could be used to justify the non patentability of genetic resources or TK obtained in contravention of the CBD.

Article 27.3. Idem	The content of Article 27.3 b) is under deep review in the TRIPS Council. The main issues that have been under discussion in the Council for TRIPS relating to TRIPS and CBD under Article 27.3b) are: a) the patentability of life forms in their natural stage and biological discoveries; b) the lack of synergies between the CBD and TRIPS; c) the definition of a *sui generis* system for plant varieties, the introduction of legal mechanisms into the patent filing procedures in order to disclose the origin of genetic resources, and d) the facilitation of environmental technologies for the protection of biodiversity and the environment.
Article 29. Conditions on patent applications	Article 29 deals with the obligation to "*disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art and may require the applicant to indicate the best mode for carrying out the invention (…)"*. Many biodiversity rich countries consider this Article allows WTO members to require the disclosure of the origin of genetic resources and of the TK in their national patent law.
Article 32. Revocation /Forfeiture	Article 30 establishes that an "*opportunity for judicial review of any decision to revoke or forfeit a patent shall be available"*. This Article does not contain the causes for revocation of a patent. This means that causes for revocation or forfeiture can be freely established by WTO Members, including cases of patents based on illegal access or use of genetic resources. In this sense, some countries consider that they have the right to revoke patents that are not consistent with Article 15 of the CBD.
Article 39. Protection of undisclosed information	Protection of undisclosed information and especially trade secrets can be a way of protecting secret TK. Trade secrets give the possibility to exercise actions against unfair competition.
Article 41.2. Enforcement measures. General obligations.	Accordingly to Article 41.2 "*Procedures concerning the enforcement of intellectual property rights shall be fair and equitable. They shall not be unnecessarily complicated or costly, or entail unreasonable time-limits or unwarranted delays*". The disclosure of the origin of genetic resources is not a burdensome procedure. Similar procedures exist in the Budapest Agreement on the International Recognition of the Deposit of Microorganisms for the purposes of the Patent Procedures and in the Biotechnology Directive of the European Union.
Article 71.1. Review and amendment.	The review of Article 71.1 can open space for a "sustainable" review and future amendment of all the TRIPS' Articles that have a relation to CBD and the protection of TK.