MODULE X
CURRENT TRIPS ISSUES*

A. INTRODUCTION

1. Current Issues

The TRIPS Agreement was not envisaged as an entirely static legal instrument: TRIPS negotiators included several provisions within the Agreement that set out a work programme for the future – the so-called "built-in agenda". And since the TRIPS Agreement entered into force, WTO Members have decided to elaborate and enhance these review processes. The most significant addition to these processes is the work on public health and access to medicines issues in line with the Doha Declaration on the TRIPS Agreement and Public Health, which is covered in Module IX. This module provides a general overview of the on-going work in the TRIPS Council and other WTO bodies on other aspects of TRIPS and public policy as of the time of writing, focussing on the following issues, which have been the most prominent:

- Geographical indications – the Article 23.4 negotiations on a system of notification and registration, a review of GI protection under Article 24.2, and work on the question of possibly extending to other products the protection provided to wine and spirits under Article 23 (so-called GI extension).

- Biodiversity and traditional knowledge – the review of the provisions on what can broadly be called "biotechnology patenting" established under Article 27.3(b) of the TRIPS Agreement, and a wider slate of related issues, especially the work on the relationship between the TRIPS Agreement and the Convention on Biological Diversity (CBD), and the protection of traditional knowledge and folklore.

- Non-violation complaints – the examination by the TRIPS Council of the scope and modalities of such disputes which is required under Article 64.3, and which has been considered by several Ministerial Conferences as mentioned in Module VIII, section C2.

- Least developed countries (LDCs) and TRIPS: specific recognition of the distinct context and interests of LDCs.

- Transfer of technology – the review mechanism set up by the TRIPS Council to monitor the implementation of the obligation, under Article 66.2, on developed country Members to provide incentives for technology transfer to LDCs.

- Electronic commerce and its implications for the TRIPS Agreement.

Since this module describes continuing processes and negotiations that were actively under way, but still unresolved at the time of writing, some of the information given in this module is likely to be superseded by subsequent developments. The current status of these issues can be checked on the WTO website, under "trade topics". In this module only, the symbol ☘ is used to identify points that may well have changed since the time of writing.
A number of other issues have been considered in the TRIPS Council, and are of ongoing interest, but are not covered in this publication for reasons of space – these include the policy dimensions of the enforcement of intellectual property rights, and the provision of technical assistance, in particular the review by the TRIPS Council of the reports made by developed country Members of the technical cooperation provided in accordance with Article 67. However, some of these issues have been covered in previous modules, notably Module I and Module VII.

The interplay between intellectual property and such policy concerns as biodiversity, the environment, access to technologies, and social and economic development touches on complex and multifaceted issues that involve diverse stakeholders. These questions are actively debated outside the WTO in many international policy forums, international and regional organizations, and national legislatures and policy processes. This Handbook focuses only on the TRIPS Agreement as such and the related work of the WTO. However, to assist in understanding this broader context, the last section of this module briefly outlines some of the work undertaken in certain multilateral organizations on these issues. No attempt is made to analyse the substance of the issues, nor to provide an account of the full range of debates and institutions that have addressed the TRIPS Agreement and public policy issues. The literature on each of these issues is vast, including a number of important resolutions, studies and reports prepared by organizations beyond the WTO; a brief guide to some of this work is provided, but this should not be taken as comprehensive or authoritative.

2. The mandates for work on TRIPS issues

To understand the continuing substantive work of the WTO on the current issues identified above, it is useful also to have some familiarity with the mandate of each policy discussion or set of negotiations – in other words, what is the procedural context and the agreed basis for each element of work, and how does this differ between issues. Specific TRIPS and IP issues have been taken up in the WTO as a result of decisions taken collectively by Members to work on them. There are several bases for ongoing work:

- some of the issues are already part of the built-in agenda, agreed to during the Uruguay Round negotiations and are part of the TRIPS Agreement itself;
- in some cases, such a built-in agenda process has been elaborated further with the agreement of all Members; and
- further, distinct, issues have been taken up as a result of decisions taken by the various WTO Ministerial Conferences.

Take, for example, the ongoing negotiations on the establishment of a notification and registration system for geographical indications for wines and spirits. The TRIPS Agreement itself in Article 23.4 mandates negotiations on a register for geographical indications for wines (hereinafter called the Register). The Singapore Ministerial Conference in 1996 broadened this mandate to cover spirits as well, and preliminary work proceeded in the TRIPS Council. Then the Doha Ministerial Conference, in 2001, incorporated this existing mandate into the overall structure of the Doha Development Agenda, and the negotiations on the register were then undertaken in a so-called “Special Session” of the TRIPS Council (see Module I, section A3).

The Doha Ministerial Conference also agreed that the WTO should work on other issues relating to TRIPS implementation - the question of extension of higher-level GI protection to products other than wines and spirits, and the matter of the relationship between TRIPS and the CBD and the protection of traditional knowledge and folklore. These issues were not part of
the original built-in agenda under the TRIPS Agreement, but were subsequently identified by some Members as in need of specific attention along with other implementation issues from the Uruguay Round package that are yet to be resolved. This led to agreement to include them in the Doha Work Programme as "outstanding implementation issues". Yet against a background of disagreement as to how they should be handled by Members, a debate continued about the exact negotiating status of these issues and therefore how work on them should proceed in the WTO. The Doha Ministerial Declaration stipulated that "negotiations on outstanding implementation issues shall be an integral part" of the Doha work programme, and that implementation issues "shall be addressed as a matter of priority by the relevant WTO bodies". It provided that "issues related to the extension of the protection of geographical indications provided for in Article 23 to products other than wines and spirits will be addressed in the Council for TRIPS. Further, the ministers instructed the Council for TRIPS "in pursuing its work programme including 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".

The substance of these two issues is discussed below. When considering the nature of the mandate on these issues, it has been a significant factor in the work of the WTO that delegations have interpreted the Doha Declaration differently – especially on the question of whether or not there is or should be a mandate to renegotiate the TRIPS text to deal with these issues. Many developing and European countries have taken the position that the outstanding implementation issues should be part of the Doha Round negotiations and should be an integral part of its package of results (the "single undertaking"). A number of other countries have maintained the view that these issues can only become negotiating subjects if the Trade Negotiations Committee decides by consensus to include them in the talks — and so far it has not done so; they have said that, under the circumstances, the work on these issues cannot be part of the results of the Doha Round.

This difference of opinion over the nature of the mandates to work on these issues means that the discussions have had to be organized carefully. These issues were taken up in the TRIPS Council until the end of 2002. Since then, they have been the subject of informal consultations chaired by the WTO Deputy Director-General and since March 2009 by the WTO Director-General himself. In 2005, the Hong Kong Ministerial Declaration took note of the work undertaken by the Director-General in his consultative process, including on issues related to the extension of the protection of geographical indications provided for in Article 23 of the TRIPS Agreement to products other than wines and spirits and those related to the relationship between the TRIPS Agreement and the CBD. It requested him to intensify his consultative process, which has continued up to the time of writing without any specific outcome.

The debate over these issues, and over the nature of the mandate to work on them, has generally been pursued by groups or coalitions of Members who share particular interests and priorities. One point of disagreement has been whether the issues should be linked together within a negotiating package or handled separately. For instance, in July 2008, a group of Members tabled a proposal (TN/C/W/52 and Add.1-3) to the Trade Negotiations Committee, which linked the Register negotiations both to the GI extension issue and to the question of the relationship between the CBD and the TRIPS Agreement. Other Members maintained that there should be no linkages drawn between these issues – for instance, that progress on the Register mandate should not be dependent on progress on the other questions – and that they should be handled separately; these same countries have generally also argued that the mandate to work on the two “implementation issues” did not extend to a mandate to initiate negotiations
on these issues. These divergent perspectives had not been resolved at the time of writing, and different groups of Members continued to differ on how to handle the implementation issues; for instance, in April 2011, just as the Trade Negotiations Committee reviewed the overall state of play of Doha Round negotiations, two groups of Members with particular interests tabled new proposals (TN/C/W/59 on TRIPS/CBD and TN/C/W/60 on GI extension) to renegotiate TRIPS in these two areas.

B. CURRENT ISSUES

1. Geographical indications

(a) Background

The ongoing work of the WTO on geographical indications has concentrated on two specific issues, relating in different ways to the higher level of protection afforded to geographical indications for wines and spirits under Article 23 of the TRIPS Agreement – first, negotiations on a multilateral system of notification and registration of geographical indications for wines and spirits; and second, the possible extension of this higher level of protection to geographical indications for other products.

As seen already in Module IV, the TRIPS Agreement established two specific processes on geographical indications, which form part of its "built-in agenda":

- under Article 23.4, the negotiations on a system of notification and registration of geographical indications for wines;
- under Article 24.2, a review by the Council for TRIPS of the application of the GI provisions of the Agreement.

In 1998, to progress the Article 24.2 review, the Council took note of a Checklist of Questions and invited those Members already bound by TRIPS provisions on geographical indications to provide responses, with other Members free to furnish replies on a voluntary basis. The Secretariat has prepared and updated a summary of these responses (document IP/C/W/253/Rev.1). This review has produced a considerable body of information on the protection of geographical indications in the national systems of Members, and has illustrated how they have employed a wide variety of legal means, including specific laws on geographical indications, trademark law, consumer protection and unfair competition law, and common law remedies. The review process has been less active since the last updated compilation in 2003, but more recently has briefly addressed bilateral agreements on GI protection that several Members have entered into.

Since the Agreement came into force in 1995, decisions by the Ministerial Conference have elaborated or augmented the built-in TRIPS agenda on geographical indications:

- the 1996 Singapore Ministerial Conference agreed to extend the scope of the register negotiations to spirits, and the 2001 Doha and 2005 Hong Kong Ministerial Conferences updated the mandate for these negotiations in the context of the overall negotiations in the Doha Round.
- the Doha Declaration also took up the question of possible extension of GI protection, stating that "issues related to the extension of the protection of geographical indications provided for in Article 23 to products other than wines and spirits will be addressed in the Council for TRIPS pursuant to paragraph 12 of this Declaration", which, in turn,
concerned "implementation-related issues and concerns raised by Members". This mandate was renewed at the Hong Kong Ministerial Conference.

These decisions therefore determined that two issues on geographical indications would be considered under the Doha mandate: the Register (in line with a pre-Doha mandate with its roots in the TRIPS Agreement itself); and extending the higher (Article 23) level of protection beyond wines and spirits, identified as an implementation issue at Doha. The different categorization of these issues, however, meant that they were dealt with in separate ways, as the following sections outline - although, as noted above, some Members have proposed that the Register negotiations be linked with the two implementation issues.

(b) The multilateral register for wines and spirits

Work on a multilateral system of notification and registration began in 1997 in line with the original mandate under Article 23.4 of the TRIPS Agreement. The Register negotiations were subsequently covered by the 2001 Doha Declaration and have since been conducted by the Special Session of the TRIPS Council as mentioned above.

In 2011, the work had evolved to a point where delegations were negotiating directly on a draft text to establish the Register (although numerous differences continued to be unresolved in these negotiations at the time of publication). Until then, the work had been characterized by debate over three sets of proposals that had been submitted earlier, expressing positions that continue to reflect the key issues under consideration:

- The European Communities (now the European Union) circulated a detailed proposal (TN/IP/W/11) in June 2005. Under this system, when a GI was registered, the TRIPS Agreement would be amended to establish, \textit{inter alia}, a "rebuttable presumption" in all Members that the term is eligible for protection and not generic in other WTO Members — except in a country that has lodged a reservation within a specified period (for example, 18 months). A reservation would have to be on permitted grounds such as that a term has become generic or does not fit the definition of a GI. If it does not make a reservation, a country would not be able to refuse protection on these grounds after the term has been registered. In a subsequent negotiating proposal (TN/C/W/52 and Ass. 1-3, noted in Section A2 above) in which a group of Members including the European Union and Switzerland put forward combined negotiating positions on the Register and the two outstanding negotiating issues, the position on the GI Register was substantially modified. It now proposed that registration of a geographical indication in the system would serve as prima facie evidence that the term met the definition of a GI in all other WTO Members, while permitting that this evidence be challenged in individual Members under national procedures without prescribing a time-limit for such challenges. It further proposed that domestic authorities should permit assertions of genericness under Article 24.6 only if these are substantiated.

- A "joint proposal" (TN/IP/W/10/Rev.4) was first submitted in 2005 and revised in 2008 and 2011 by another group of Members. This group does not want to amend the TRIPS Agreement. Instead, it proposes a decision by the TRIPS Council to set up a voluntary system where a notified GI would be registered in a database. Members choosing to participate in the system would commit to ensure that its procedures include the provision to consult the database when taking decisions on protection in their own countries. Non-participating Members would be "encouraged" but not "obliged" to consult the database.
Hong Kong, China proposed a compromise (TN/IP/W/8), under which a registered GI term would enjoy a more limited "presumption" than under the previous EC proposal, and only in those countries choosing to participate in the system.

The WTO Secretariat prepared two working papers to assist the negotiations, one a side-by-side comparison of the three proposals (TN/IP/W/12), and the other a compilation of the issues raised and points made in these negotiations (TN/IP/W/12/Add.1 and Corr.1).

At the heart of the negotiations lie several key issues, on which groups of Members have continued to differ:

- "legal effect" – when a GI is registered in the system, what consequences, if any, would its registration have for WTO Members?
- "participation" – could Members choose not to participate in the system, or would it be mandatory for all Members to recognize the Register in their domestic systems?
- questions concerning the kind of information that would be required for a notification and how the Register would be administered, including how its costs would be covered; and
- considerations such as "special and differential treatment", i.e. the kind of provisions that would assist and support developing countries and LDCs in particular.

When the negotiations moved to a single composite text in early 2011, this working draft incorporated a range of provisions proposed and supported by different delegations, thus representing these diverse options and issues within one document. One version of this draft, including many unresolved textual elements, was circulated to the Trade Negotiations Committee in April 2011 as part of a general review of the state of play of the Doha negotiations (TN/IP/21).

(c) Extending the "higher level of protection" beyond wines and spirits

Module IV explains the difference between Article 22 protection for geographical indications, and the "higher" protection prescribed for wine and spirit geographical indications under Article 23. The question of extending this higher protection to other products was identified as an implementation issue in the Doha Declaration. A number of countries - including the European Union and Switzerland and several developing countries - have called to renegotiate TRIPS to broaden the coverage of goods covered by Article 23 to other products. They have argued for the higher level of protection as a way to better defend the marketing terms for their locally based products and to counter more effectively the 'usurpation' of geographical terms by countries adopting them as generic descriptions for similar products. The European Communities circulated a formal proposal (document TN/IP/W/11) on this extension issue in 2005. The TN/C/W/52 proposal in 2008 called for extension of Article 23 protection "for all products, including the extension of the Register". It proposed negotiations to amend the TRIPS Agreement to apply Article 23 to geographical indications for all products as well as to apply to these the exceptions provided in Article 24 of the TRIPS Agreement *mutatis mutandis*. As seen above, a further formal proposal to renegotiate the TRIPS Agreement to extend GI protection was circulated by a number of active proponents in April 2011 (TN/C/W/60).

The Members opposing extension essentially comprise those countries that have opposed a stronger version of the Register. They have argued that the existing (Article 22) level
of protection is adequate, and cautioned that providing enhanced protection would be a burden and would disrupt existing legitimate marketing practices. They have also rejected the claim of "usurpation", arguing that in some cases migrants have taken the methods of making the products and the names with them to their new homes and have been using them there in good faith. (See also Module IV, section A2.) Further, they have maintained that there is no agreement on a mandate to undertake negotiations on the TRIPS Agreement text on this issue, and that the only negotiating mandate concerns the register for wine and spirit geographical indications.

The Secretariat has compiled the issues raised and the views expressed in this debate, in document WT/GC/W/546-TN/C/W/25. More recently, the issue has been considered in the consultative process convened by the WTO Director-General since March 2009. While these consultations are informal, their proceedings have been reported periodically by the Director-General to the General Council and TNC as well as published on the WTO website, including a report by the Director-General in April 2011 as part of a general stocktaking process at that time (WT/GC/W/633-TN/C/W/61). Reports from the consultations have noted the continuing differences between Members, with emphasis in the discussions lying on the analysis and clarification of the technical and legal aspects of the question of extension of GI protection and the existing character of national systems of protection.

2. The "Triplets": Biotechnology, Traditional Knowledge, Biodiversity

In establishing the forward work programme for the WTO on TRIPS issues, the Doha Declaration referred to three distinct but closely interrelated issues, which have become known informally as the "triplets". Paragraph 19 of the Doha Declaration referred to the Article 27.3(b) review that was already required in the text of the TRIPS Agreement itself, and instructed the TRIPS Council in pursuing its work programme including 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.

The Doha Declaration directed the TRIPS Council to be guided in this work by the objectives and principles set out in Articles 7 and 8 of the TRIPS Agreement and to take fully into account the development dimension.

This section looks at these three issues in turn – the Article 27.3(b) review, traditional knowledge and folklore, and the TRIPS-CBD relationship.

(a) Article 27.3 (b) Review

Article 27.3 (b) concerns the scope of permissible exceptions to patentable subject matter in biotechnology patenting, and leaves open an option for Members to rule out patents on certain biological inventions within their national IP systems. In particular, it provides for optional exclusions from the scope of patentable subject matter for plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, it does require "protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof." As part of the built-in TRIPS agenda, this subparagraph became due for review in 1999, four years after the Agreement came into force. When this review commenced,
it was clear that WTO Members had a wide range of perspectives and concerns in the general field of biotechnology patenting. The 2001 Doha Declaration broadened the discussion, in setting the mandate for future work of the Organization, linking this review to the TRIPS-CBD and traditional knowledge issues, as outlined in section A2 above.

The TRIPS Council prepared for the Article 27.3 (b) review in 1998 through an information-gathering exercise, and invited Members that were already under an obligation to apply the provision to provide information on how the matters addressed in this provision were presently treated in their national law. While it was up to each Member to decide how to provide this information, the Secretariat was asked to prepare an illustrative list of questions to assist Members to prepare their contributions (see IP/C/W/122). These questions covered a range of legal and technical matters concerning, first, the patent protection of plant and animal inventions, and second, the protection of plant varieties. Following two rounds of contributions by Members, a revised compilation of the answers received was prepared by the Secretariat in 2003 (IP/C/W/273/Rev.1), including a synoptic table to illustrate the choices made by individual Members in this area of IP law.

The TRIPS Council maintains this review on its agenda. Discussions, which have been inconclusive, have included debate on:

- patentability of certain life forms and whether there should be exclusions for any such inventions;
- how to strike a balance, in the protection of plant varieties, between private and community interests, and other issues such as farmers’ rights and maintaining biodiversity.

(b) Traditional Knowledge and Folklore

In line with the instructions given in the Doha Declaration, the TRIPS Council has continued to work on the protection of traditional knowledge and folklore since 2002. The Secretariat was instructed to prepare summaries of the wide range of issues and perspectives that have been covered in this debate. The most recent update, document IP/C/W/370/Rev.1, issued in 2006, covered general issues relating to the protection of traditional knowledge, the grant of patents relating to traditional knowledge, and consent and benefit sharing, including use of the existing IP system, protecting traditional knowledge under a sui generis system (a distinct form of protection created specifically for traditional knowledge), and information on Members’ national legislation, practices and experiences.

The general issues covered, for instance, the question of why there is need for international action on the protection of traditional knowledge and folklore; and the international forum/forums most appropriate to pursue such a work. Proponents of international action to protect traditional knowledge and folklore were reported as voicing

- concern about the granting of patents or other IPRs covering traditional knowledge to persons other than those indigenous peoples or communities who have originated and legitimately control the traditional knowledge;
- concern that traditional knowledge is being used without the authorization of the indigenous peoples or communities who have originated and legitimately control it and without proper sharing of the benefits that accrue from such use.
The issue remains on the agenda of the TRIPS Council but discussion has been relatively limited more recently, in contrast to the discussion in other processes, such as the work of the WIPO Intergovernmental Committee on IP and Genetic Resources, Traditional Knowledge and Folklore, which has been undertaking negotiations on legal instruments in this field.

(c) Relationship between the TRIPS Agreement and the Convention on Biological Diversity

The third of the "triplets" issues concerns the relationship between the TRIPS Agreement and the CBD; like the other two issues, this has remained on the agenda of the TRIPS Council as a distinct item since 2002, although it deals with issues that had earlier been raised under the Article 27.3(b) review. A comprehensive summary of issues raised and points made has been prepared by the Secretariat, and was issued in revised form in 2006 as document IP/C/W/368/Rev.1. This summary identified two general issues raised concerning the overall relationship between the TRIPS Agreement and the CBD:

- whether or not there is conflict between the TRIPS Agreement and the CBD;
- whether something needs to be done, at least on the TRIPS side, to ensure that the two instruments are applied in a non-conflicting and mutually supportive way, and if so, what should be done.

The views expressed on these two questions were grouped into four broad categories:

- that there is no conflict between the two Agreements and governments can implement the two in a mutually supportive way through national measures;
- that there is no conflict between the two Agreements and, while governments can implement the two in a mutually supportive way through national measures, further study is required to determine whether any international action in relation to the patent system is called for;
- that there is no inherent conflict between the two Agreements but there is a case for international action in relation to the patent system in order to ensure or enhance, in their implementation, the mutual supportiveness of both Agreements. There are differences of view on the exact nature of the international action needed, including on whether or not an amendment is needed to the TRIPS Agreement, to promote the objectives of the CBD;
- that there is inherent conflict between the two instruments, and the TRIPS Agreement needs to be amended to remove such conflict.

A number of proposals have been put forward and extensively debated. It is argued that these proposals reinforce the relationship between the CBD and the TRIPS Agreement, preclude possible conflicts in the practical implementation of the two treaties, or deal with claimed areas of conflict or tension between them. Proposals include amending the TRIPS Agreement to introduce a mandatory requirement for patent applicants to disclose the source and country providing genetic resources or traditional knowledge used in inventions, and to demonstrate that they had obtained prior informed consent from the competent authority in the country of origin and entered into fair and equitable benefit-sharing arrangements or that they followed national legal requirements.

Extensive substantive debate has ensued on these issues, including through a series of submissions by Members to the TRIPS Council, concentrating in particular on:
• how to deal with instances of erroneous patenting of genetic resources and associated traditional knowledge; and

• the principles of prior informed consent and equitable benefit sharing under the CBD, and whether, and if so how, they should be recognized explicitly or directly applied in the TRIPS Agreement or through its implementation at the national level.

More recent discussions on these questions have focussed especially on:

• use of national solutions, including legislation on genetic resources access and benefit sharing and contracts to enforce the principles of prior informed consent and equitable sharing of benefits;

• the use of databases on traditional knowledge and genetic resources to preclude erroneous patents on this subject matter;

• proposals to amend the TRIPS Agreement to oblige Members to require that a patent applicant for an invention relating to genetic or biological materials or to traditional knowledge provide information on source and origin, prior informed consent and equitable benefit sharing.

As already noted above, a negotiating proposal, tabled in the TNC in 2008 by a number of Members (TN/C/W/52), linked this issue to the two current GI issues. It proposed negotiations to amend the TRIPS Agreement to introduce a mandatory disclosure requirement concerning the country providing/source of genetic resources, and/or associated traditional knowledge, and also referred to prior informed consent and access and benefit sharing. Other Members disagreed that there was, or should be, a mandate to negotiate a TRIPS amendment on this issue, and disagreed that such a disclosure mechanism was the best way to ensure compliance with prior informed consent and equitable benefit sharing obligations. More recently, as part of the April 2011 stocktaking exercise, a group of active proponents of the disclosure approach tabled in the Trade Negotiations Committee a new formal proposal to revise the TRIPS Agreement to introduce a mandatory disclosure mechanism, linking this issue also with the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization which was concluded in October 2010 under the aegis of the CBD (TN/C/W/59).

Along with the issue of GI extension, the TRIPS-CBD relationship has also been considered in the consultative process convened by the Director-General. As noted above, while these consultations are informal, their proceedings have been reported periodically, including a report by the Director General as part of the general stocktaking of Doha-related work in April 2011. Reports from the consultations have noted the continuing differences between Members on the choice between these options, although general consensus has been reported concerning the principle of equitable benefit sharing and the need to avoid erroneous patenting. Reports have described how the consultations have focussed on the analysis and clarification of the technical and legal aspects of the questions of erroneous patenting and misappropriation, and the different approaches that have been put forward in the general debate – the tailored disclosure mechanism, greater use of databases to preclude erroneous patents on genetic resources and traditional knowledge subject matter, and the national contract-based approach to enforcing access and benefit-sharing obligations.
3. Non-violation complaints

Module VIII, section C2 discussed the issue of non-violation and situation complaints relating to the TRIPS Agreement. As noted in that module, Article 64.2 of the TRIPS Agreement gave a moratorium on the application of such complaints to the TRIPS Agreement for a period of five years and Article 63.3 instructed the TRIPS Council to examine the extent and manner ("scope and modalities") in which complaints of this type could be made; it required the TRIPS Council to make recommendations to the General Council by the end of 1999. The "moratorium" on the use of non-violation and situation complaints has been extended a number of times, namely by the Doha Ministerial Conference in 2001, by the WTO General Council in 2004 as part of the so-called July 2004 package, by the Hong Kong Ministerial Conference in 2005 and, most recently, by the Ministerial Conferences in Geneva in 2009 and 2011. At the same time, the TRIPS Council has been instructed to continue its examination of the scope and modalities for this type of complaints and to make recommendations. Despite extensive analysis and debate on this issue (see in particular the Summary Note by the Secretariat, document IP/C/W/349/Rev.1), WTO Members remain divided on whether non-violation or situation complaints should apply to the TRIPS Agreement. Debate therefore addresses not merely scope and modalities of such disputes, but whether they should be admissible at all within the WTO dispute settlement system.

4. Least-developed countries and TRIPS

The negotiators of the TRIPS Agreement recognized the particular concerns and needs of LDCs concerning the IP system. The preamble of the TRIPS Agreement already acknowledges LDCs' particular need for maximum flexibility in implementing laws and regulations domestically. The objective was to enable them to create a sound and viable technological base.

Consequently, the TRIPS Agreement obliged developed countries to provide incentives for technology transfer to least developed countries (Article 66.2). It also allowed LDCs ten years from 1995 to apply the bulk of TRIPS obligations, with the possibility that this transition period might be extended in response to a specific request. With this transition period due to expire in January 2006, the TRIPS Council decided in 2005 to extend this period until July 2013 for all LDCs, following a request by the LDC Members. The 2011 Ministerial Conference invited the TRIPS Council to give "full consideration" to a request for a further extension. Separately, pursuant to the directions given to it in the 2001 Doha Declaration on TRIPS and Public Health, the TRIPS Council had already, in 2002, extended the period to January 2016 for LDCs to implement and enforce TRIPS provisions relating to patents and test data with respect to pharmaceutical products.

When the TRIPS Council agreed to the general extension for LDCs until July 2013, it also set up a process to help LDC Members implement TRIPS within their national IP regimes, on the basis of their individual priority needs, and to enhance the necessary technical cooperation to address those needs. The TRIPS Council's decision (document IP/C/40) recognized the special needs and requirements of LDC Members, the economic, financial and administrative constraints that they continue to face, and their need for flexibility to create a viable technological base, as well as their continuing needs for technical and financial cooperation so as to enable them to realize the cultural, social, technological and other developmental objectives of intellectual property protection. The decision laid out three operational elements:

- LDCs were asked to provide the TRIPS Council with as much information as possible on their individual priority needs for technical and financial cooperation in order to assist them taking steps necessary to implement the TRIPS Agreement. Between
2007 and mid-2011, six LDCs provided this information to the TRIPS Council in the form of comprehensive needs assessments.

- Developed countries were asked to provide technical and financial help in order to “effectively address the needs identified” by LDC Members. Article 67 of the TRIPS Agreement already created a general obligation on developed country Members to provide technical and financial cooperation for developing country and LDC Members, “on request and on mutually agreed terms and conditions.” This additional decision focussed especially on the specific needs identified by LDC Members, and recognized that technical cooperation should be demand-driven, centred on actual requirements each LDC identifies, in line with a general WTO policy by which assistance is provided upon request.

- The WTO was asked to enhance its cooperation with the World Intellectual Property Organization (WIPO) and other relevant international organizations, with a view to making technical assistance and capacity building as effective and operational as possible. WIPO and the WTO have cooperated extensively on technical assistance, in response to the request and based on a Cooperation Agreement adopted in 1995, as well as a Joint Initiative on Technical Cooperation for Least Developed Countries, launched in June 2001. Other important international partners in technical cooperation also include UNCTAD and the WHO, the latter on TRIPS and public health issues.

5. The TRIPS Agreement and transfer of technology

Developing countries, in particular, see technology transfer as part of the bargain in which they have agreed to protect intellectual property rights. The TRIPS Agreement includes a number of provisions on this. The preamble recognizes the underlying public policy objectives of national systems for the protection of intellectual property, including developmental and technological objectives. Article 7 (“Objectives”) states that the protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.

As seen in Module I, section D.3, Article 66.2 of TRIPS defines an obligation specifically for developed country Members of the WTO to provide “incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer” to LDC Members, to enable those countries “to create a sound and viable technological base”. Reflecting continuing interest in the implementation of this provision, ministers agreed at the 2001 Doha Ministerial Conference that the TRIPS Council would “put in place a mechanism for ensuring the monitoring and full implementation of the obligations” under Article 66.2. The Council duly adopted a decision setting up this mechanism in February 2003. It details the information developed countries are to supply for the review by the Council at annual end-of-the-year meeting. More details on this monitoring mechanism and where the resulting documentation can be found are provided in Appendix 1, section 5.a.

At the same time, various other WTO decisions have raised the question of technology transfer and TRIPS, reaffirming the commitment to implement Article 66.2, such as the Doha Declaration on TRIPS and Public Health, and the ensuing 2003 and 2005 decisions on TRIPS and public health.
6. Electronic commerce

The Ministerial Conference adopted a "Declaration on Global Electronic Commerce" in 1998. Ministers recognized that global electronic commerce was growing and creating new opportunities for trade, and urged the General Council to establish a comprehensive work programme to examine all trade-related issues relating to global electronic commerce, taking into account the economic, financial, and development needs of developing countries. They also declared that Members would continue their current practice of not imposing customs duties on electronic transmissions. The WTO General Council subsequently established a Work Programme on Electronic Commerce (WT/L/274) for the relevant WTO bodies, including the TRIPS Council. It provided that "the Council for TRIPS shall examine and report on the intellectual property issues arising in connection with electronic commerce. The issues to be examined shall include:

- protection and enforcement of copyright and related rights;
- protection and enforcement of trademarks;
- new technologies and access to technology."

The issue of electronic commerce was addressed by the TRIPS Council as a standing item on its agenda from 1998 to 2003, and the Council provided a series of reports to the General Council. The reports reflected a view of Members that the novelty and complexity of the intellectual property issues arising in connection with electronic commerce were such that continued further study was required by the international community to better understand the issues involved, and noted the related work of WIPO. Some specific issues discussed included transfer of technology, the potential application of the TRIPS Agreement's provisions relating to anti-competitive practices in the context of electronic commerce and the Internet, the WIPO Copyright Treaty ("WCT") and the WIPO Performances and Phonograms Treaty ("WPPT"), the use of trademarks on the Internet, domain names, and the liability of Internet service providers. Details of these issues, and the extensive documentation circulated within the TRIPS Council, are provided in documents IP/C/W/128 and IP/C/W/128/Add.1. No specific conclusions or follow-up actions emerged from the TRIPS Council discussions.

C. The TRIPS Agreement in other multilateral policy processes

The Handbook focusses on the TRIPS Agreement as one of the legal agreements within the World Trade Organization system, and – for reasons of space and design – it does not provide details of the wider debates, negotiations and policy discussions that touch on the provisions of the TRIPS Agreement and their implementation in national law. However, even when looking at the Agreement in isolation, it is important to understand that the TRIPS Agreement has been considered by a range of international and regional organizations beyond the WTO. Without attempting to be comprehensive or authoritative, this section provides a brief overview of some of these discussions outside of the WTO which have considered the TRIPS Agreement, usually in relation to some wider public policy issues, such as health, the environment or human rights. This section only provides a general and illustrative set of examples of the way TRIPS has been considered in other policy processes – it is neither complete nor fully representative.
1. The TRIPS Agreement and public health beyond the WTO

The TRIPS Agreement itself and the Doha Declaration on TRIPS and Public Health have been extensively analysed and debated in forums beyond the WTO. Foremost amongst these is the World Health Organization (WHO), which has considered the TRIPS Agreement extensively in its work on innovation, access to medicines, and public health. The TRIPS provisions on patenting of pharmaceuticals, exceptions and limitations to patent rights, and the protection of clinical trial data have been central in the work of the WHO on public health and intellectual property issues. Particular processes include:

- The Commission on Intellectual Property Rights, Innovation and Public Health, which was established by the World Health Assembly (WHA) in 2003. (The WHA is the decision-making body of the WHO, analogous to the WTO Ministerial Conference.) Many of the working papers of the Commission dealt with TRIPS-related issues, and its final report, delivered in 2006, extensively discussed the TRIPS Agreement and the Doha Declaration on TRIPS and Public Health throughout.

- The Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (GSPOA) was established by the World Health Assembly in 2008. This strategy notes, as part of its context, that:

  The Doha Ministerial Declaration on the TRIPS Agreement and Public Health confirms that the agreement does not and should not prevent Members from taking measures to protect public health. The declaration, while reiterating commitment to the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), affirms that the Agreement can and should be interpreted and implemented in a manner supportive of the rights of WTO Members to protect public health and, in particular, to promote access to medicines for all. Article 7 of the TRIPS agreement states that "the protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations".

- This strategy refers to the TRIPS Agreement in several areas, including on transfer of health-related technology, the application and management of intellectual property to contribute to innovation and promote public health, and improving delivery and access for health products. Furthermore, the plan of action to give effect to the strategy notes the role of the TRIPS Agreement, its provisions and flexibilities, in a number of the specific actions that constitute the overall plan.
The WHO Secretariat is charged with the practical implementation of the GSPOA, which it undertakes in part through cooperation with other international organizations, including the WTO.

2. TRIPS and human rights

The principal mechanism within the United Nations system dealing with human rights is the Human Rights Council, an inter-governmental body responsible for strengthening the promotion and protection of human rights. It was created by the UN General Assembly in 2006, to replace the former Human Rights Commission. Both human rights bodies have considered the TRIPS Agreement, from the perspective of several areas of human rights. Those that have been most discussed include:

- The right to benefit from moral and material interests resulting from creative work
- The right of everyone to the enjoyment of the highest attainable standard of physical and mental health (the "right to health")
- The right to adequate food
- Rights of Indigenous Peoples


The Council (and formerly the Commission) appoints "Special Rapporteurs" to look into specific human right issues. Special Rapporteurs on the Right to Food, the Right to Health, and the Rights of Indigenous Peoples have discussed various aspects of the TRIPS Agreement.

The United Nations Committee on Economic, Social and Cultural Rights adopted in 2005 a General Comment on Article 15.1(c) of the International Covenant on Economic, Social and Cultural Rights that concerns an author’s right to benefit from the protection of moral and material interests resulting from his or her creative work (UN document E/C.12/GC/17). The purpose of the General Comment is to assist States that are parties to the Covenant to implement its provisions. It explores, inter alia, the scope of protection of the moral and material interests in relation to intellectual property rights under national legislation or international agreements, including the TRIPS Agreement.

Other organizations dealing with human rights issues have also considered the TRIPS Agreement: for instance, the UNESCO Universal Declaration on Human Rights and Bioethics cites both the TRIPS Agreement and the Doha Declaration on TRIPS and Public Health in its preamble.

3. TRIPS and development issues

The relationship between intellectual property systems and economic, social and cultural development has been a cross-cutting question, analysed and debated throughout the United Nations system, and other intergovernmental and regional organizations. These discussions frequently consider the provisions, role and implications of the TRIPS Agreement, with specific focus on the situation of developing countries and least developed countries in particular. The development implications of the TRIPS Agreement have been considered
extensively in many forums within WIPO, since the Agreement came into force in 1995, and especially since the cooperation agreement between the WTO and WIPO on TRIPS, which came into force the following year. For example, when, in 2007, the General Assembly of WIPO adopted 45 recommendations relating to the WIPO Development Agenda, these recommendations included the following:

- Within the framework of the agreement between WIPO and the WTO, WIPO shall make available advice to developing countries and LDCs, on the implementation and operation of the rights and obligations contained in the TRIPS Agreement, as well as on the understanding and use of flexibilities.

- To approach intellectual property enforcement in the context of broader societal interests and especially development-oriented concerns, with a view that "the protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations", in accordance with Article 7 of the TRIPS Agreement.

The United Nations Conference on Trade and Development (UNCTAD) has also undertaken a wide range of policy analysis and technical cooperation in relation to the TRIPS Agreement and development issues. Its programme on technical cooperation aims at improving understanding of the development implications of the TRIPS Agreement, and strengthening the analytical and negotiating capacity of developing countries so that they are better able to participate in IPRs-related negotiations in an informed fashion in furtherance of their sustainable development objectives.

Other elements of the United Nations system have worked extensively on the TRIPS Agreement – these include the United Nations Development Programme (UNDP) and the United Nations Department of Economic and Social Affairs (UNDESA).

4. Intellectual property and competition policy

There are several forums where the application of competition policy provisions in the area of IP is discussed - these include WIPO, UNCTAD and the WTO; the interplay between competition policy and the IP system is one element of the WIPO Development Agenda. At the level of individual WTO Members, the application of competition law vis-à-vis intellectual property has, in many cases, been the subject of relevant guidelines in addition to enforcement proceedings and/or policy discussion and debate. It should, nonetheless, be emphasized that approaches to these issues vary across WTO Members and, indeed, are by no means settled in all jurisdictions. Within the WTO, a number of Members have reported on their national experiences in relation to the Working Group on the Interaction between Trade and Competition Policy (WGTCP).

5. TRIPS and environmental agreements

The provisions of the TRIPS Agreement, especially those concerning patents and plant variety rights, have been considered in a number of multilateral environmental forums, and by the United Nations Environment Programme (UNEP), as the United Nations system's designated entity for addressing environmental issues at the global and regional level. Two specific clusters of issues concerning TRIPS and environmental agreements have received particular attention:
• Policy discussions concerning the Convention on Biological Diversity (CBD) have considered the TRIPS Agreement in the context of two sets of issues in particular – firstly, the intellectual property issues relating to the CBD’s principles of prior informed consent and equitable sharing of benefits from the use of genetic resources and associated traditional knowledge, within its work program on access and benefit-sharing (a work program which also led, in October 2010, to the conclusion of the Nagoya Protocol) and, secondly, the role of incentives and other technology transfer mechanisms in relation to provisions of the CBD dealing with access to and transfer of technologies that are relevant to the conservation and sustainable use of biological diversity or that make use of genetic resources and do not cause significant damage to the environment, as part of a CBD cross-cutting programme on technology transfer and cooperation.

• The development, diffusion and transfer of technology relating to climate change mitigation and adaptation has been a key issue in multilateral work on climate change since the conclusion of the United Nations Framework Convention on Climate Change (UNFCCC) in 1992. More recent negotiations under the UNFCCC have paid attention to the role of and impact of intellectual property, and the patent system especially, in relation to innovation and diffusion of technology relevant to climate change mitigation and adaptation. Policy discussions concerning climate change have therefore included consideration of TRIPS provisions on the scope of patentable subject matter, flexibilities such as compulsory licensing, and mechanisms for technology transfer.