

MODULE XI

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 in line with the Doha Declaration on the TRIPS Agreement and Public Health (Doha Declaration),¹³¹ which is covered in Module X. Members have also raised topical policy issues as *ad hoc* agenda items for the TRIPS Council to consider.

This module provides a general overview of the ongoing work in the TRIPS Council and other WTO bodies on other aspects of TRIPS and public policy as of the time of writing, focusing on the following issues, which have been the most prominent:

- GIs – 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 CBD, and the protection of traditional knowledge (TK) 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 IX, section C2.
- LDCs and TRIPS – specific recognition of the distinct context and interests of LDCs.

¹³¹ [WT/MIN\(01\)/DEC/2](#), reproduced in Annex 6 to this Guide.

- 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.
- Issues raised by WTO members in relation to innovation, the public interest and climate-related technology.

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'.

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 IPRs, and the provision of technical assistance, in particular the review by the TRIPS Council of the reports made by developed country members on 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 VIII.

The interplay between IP 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 stake holders. These questions are actively debated outside the WTO in many international policy forums, international and regional organizations, and national legislatures and policy processes. This Guide 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 this differs 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;
- further, distinct, issues have been taken up as a result of decisions taken by the various WTO Ministerial Conferences; and
- Other topical issues have been added to the TRIPS Council's agenda at the request of certain members.

Take, for example, the ongoing negotiations on the establishment of a notification and registration system for GIs for wines and spirits. The TRIPS Agreement itself in Article 23.4 mandates negotiations on a register for GIs for wines (hereinafter '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 E2).

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'.¹³² 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

¹³² [WT/MIN\(01\)/DEC/1](#), para. 12.

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’.¹³³

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 Ministerial 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 members have maintained the view that these issues can only become negotiating subjects if the Trade Negotiations Committee (TNC) 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. When the Council failed to reach agreement on how to work on these issues, a series of informal consultations was undertaken under the authority of the Director-General of the WTO. These were initially chaired by a Deputy Director-General of the WTO and between 2009 and 2011 by the 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 GIs 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 continued through to 2011 without any specific outcome, and the matter has not been taken up directly since then.

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 proposal¹³⁴ to the TNC, 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

¹³³ [WT/MIN\(01\)/DEC/1](#), paras. 18-19.

¹³⁴ [TN/C/W/52](#) and Add.1-3.

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 have not been resolved at the time of writing, and different groups of members continued to differ on how to handle the implementation issues. In April 2011, just as the TNC was reviewing the overall state of play of Doha Round negotiations, two groups of members with particular interests tabled new proposals¹³⁵ to renegotiate TRIPS in these two areas. However, there has been no significant engagement since then on these issues within the WTO system, even though these have been the subject of diverse negotiation, legislation and policy development in many other contexts.

B Current issues in the WTO's work on TRIPS and related areas

1 Geographical indications

(a) Background

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

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

- under Article 23.4, the negotiations on a multilateral system of notification and registration of GIs for wines;
- under Article 24.2, a review by the TRIPS Council 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 GIs to provide responses, with other members free to furnish replies on a voluntary basis.¹³⁶ 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 GIs in the domestic systems of members, and has illustrated how they have employed a wide variety of legal means, including specific laws on GIs, trademark law, consumer protection and unfair competition law, and common law remedies. The review process has been less active since the last updated compilation

¹³⁵ [TN/C/W/59](#) on TRIPS/CBD and [TN/C/W/60](#) on GI extension.

¹³⁶ The responses from members have been circulated in document [IP/C/W/117](#), addenda, supplements and revisions.

in 2003, but has also turned to bilateral agreements on GI protection that a number of 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 GIs:

- 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 Ministerial 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’.¹³⁷ This mandate was renewed at the Hong Kong Ministerial Conference.

These decisions therefore determined that two issues on GIs 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 Ministerial 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:

¹³⁷ [WT/MIN\(01\)/DEC/1](#), paras. 12 and 18.

- The European Communities (now the European Union) circulated a detailed proposal¹³⁸ in June 2005. Under this system, when a GI was registered, the TRIPS Agreement would be amended to establish, *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, eighteen 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 proposal¹³⁹ in which a group of members including the European Union and Switzerland put forward combined negotiating positions on the Register and the two outstanding implementation issues, the position on the GI Register was substantially modified. It now proposed that registration of a GI 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’¹⁴⁰ 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 their procedures include a provision to consult the database when taking decisions on protection in their own territories. Non-participating members would be ‘encouraged’ but not ‘obliged’ to consult the database.
- Hong Kong, China proposed a compromise,¹⁴¹ 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,¹⁴² and the other a compilation of the issues raised and points made in these negotiations.¹⁴³

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

¹³⁸ [TN/IP/W/11](#).

¹³⁹ See fn 134 above.

¹⁴⁰ [TN/IP/W/10/Rev.4](#).

¹⁴¹ [TN/IP/W/8](#).

¹⁴² [TN/IP/W/12](#).

¹⁴³ [TN/IP/W/12/Add.1](#) and Corr.1.

- ‘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 TNC in April 2011 as part of a general review of the state of play of the Doha negotiations.¹⁴⁴

Since 2011, WTO members have remained divided over the scope and the substance of the Register. Renewed efforts to negotiate an agreement following the 2013 Bali Ministerial Conference have been unsuccessful thus far. Members have largely continued to reiterate known, well-established positions, as indicated in the annual reports of the Chairperson of the Special Session of the TRIPS Council.¹⁴⁵ Some members have also conditioned work on the Register with progress on the TRIPS implementation issues of (i) extending higher-level GI protections (discussed immediately below) and (ii) the relationship between the TRIPS Agreement and the CBD (see section 2(c) below).

Meanwhile, members have entered into numerous bilateral and regional agreements on GI protection, the Geneva Act of the WIPO Lisbon Agreement has entered into force, and several members have implemented enhanced protections for GIs domestically.

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

Module IV explains the difference between Article 22 protection for GIs, and the ‘higher’ protection prescribed for wine and spirit GIs under Article 23. The question of extending this higher protection to other products was identified as an implementation issue in the Doha Ministerial Declaration. A number of members – including the European Union, 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

¹⁴⁴ [TN/IP/21](#).

¹⁴⁵ See, e.g. [TN/IP/27](#).

the ‘usurpation’ of geographical terms by members adopting them as generic descriptions for similar products. The European Communities circulated a formal proposal¹⁴⁶ on this extension issue in 2005. The 2008 proposal which put forward combined negotiating positions on the Register, GI extension, and the relationship between TRIPS and the CBD,¹⁴⁷ 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 GIs 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 2011.¹⁴⁸

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 GIs.

The Secretariat has compiled the issues raised and the views expressed in this debate in document [WT/GC/W/546-TN/C/W/25](#). The issue was also considered in a consultative process convened by the WTO Director-General from March 2009 through 2011. While these consultations were informal, their proceedings were 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.¹⁴⁹ 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.

¹⁴⁶ [TN/IP/W/11](#).

¹⁴⁷ See fn 134 above.

¹⁴⁸ [TN/C/W/60](#).

¹⁴⁹ [WT/GC/W/633-TN/C/W/61](#).

2 The 'triplets': biotechnology, traditional knowledge, biodiversity

In establishing the forward work programme for the WTO on TRIPS issues, the Doha Ministerial Declaration referred to three distinct but closely interrelated issues, which have become known informally as the 'triplets'. Paragraph 19 of the Doha Ministerial 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:

[I]n 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 71.1.¹⁵⁰

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 Ministerial 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

¹⁵⁰ [WT/MIN\(01\)/DEC/1](#), para. 19.

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.¹⁵¹ Certain members developed another illustrative list of questions and invited interested members to submit responses.¹⁵² These two lists of questions cover 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 2003,¹⁵³ 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:

- the patentability of certain life forms and whether there should be exclusions for any such invention; and
- 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 TK 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 TK, the grant of patents relating to traditional knowledge, and consent and benefit sharing, including use of the existing IP system, protecting TK under a *sui generis* system (a distinct form of protection created specifically for TK), 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 TK and folklore; and the international forum/forums most appropriate to pursue such work. Proponents of international action to protect TK and folklore were reported as voicing concerns:

- about the granting of patents or other IPRs covering TK to persons other than those indigenous peoples or communities who have originated and legitimately control the TK; and

¹⁵¹ [IP/C/W/122](#).

¹⁵² [IP/C/W/126](#).

¹⁵³ [IP/C/W/273/Rev.1](#).

- that TK 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 (IGC), which has been undertaking negotiations on legal instruments in this field. Certain members have expressed the belief that the IGC is the most appropriate forum for advancing technical discussions on these topics.

(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](#) and Corr.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; and
- 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 members can implement the two in a mutually supportive way through domestic measures;
- that there is no conflict between the two Agreements and, while members can implement the two in a mutually supportive way through domestic 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; and

- 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 member providing genetic resources or TK 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 domestic level.

More recent discussions on these questions have focused especially on:

- the 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 TK and genetic resources to preclude erroneous patents on this subject matter; and
- 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 TK 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,¹⁵⁴ 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 TK, 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

¹⁵⁴ See fn 134 above.

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. As part of the April 2011 stocktaking exercise, a group of active proponents of the disclosure approach tabled in the TNC 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.¹⁵⁵ As of the time of this writing, members have been unable to agree as to whether the CBD Secretariat should be invited to brief the TRIPS Council on the Nagoya Protocol.

Along with the issue of GI extension, the TRIPS–CBD relationship was also considered in the consultative process convened by the Director-General, which was particularly active between 2009 and 2011. As noted above, while these consultations were informal, their proceedings were reported periodically. The final stage of active consultations was marked by the release of a report in April 2011 by the Director-General as part of the general stocktaking of Doha-related work at that time. Reports from the consultations noted the continuing differences between members on the choice between these options, although general consensus was reported concerning the principle of equitable benefit sharing and the need to avoid erroneous patenting. Reports described how the consultations focused on the analysis and clarification of the technical and legal aspects of the questions of erroneous patenting and misappropriation, and the different approaches that were put forward in the general debate – the tailored disclosure mechanism, greater use of databases to preclude erroneous patents on genetic resources and TK subject matter, and the national contract-based approach to enforcing access and benefit sharing obligations.

3 *Non-violation complaints*

Module IX, 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 64.3 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.¹⁵⁶ At the same time, the TRIPS Council has been instructed to continue its examination of the scope and modalities for this type of complaint, and to make recommendations.

¹⁵⁵ [TN/C/W/59](#).

¹⁵⁶ The 'moratorium' on the use of non-violation and situation complaints was extended at the Doha Ministerial Conference in 2001; by the General Council in 2004 as part of the so-called July 2004 package; by the Ministerial Conferences in Hong Kong, China in 2005; Geneva in 2009 and 2011; Bali in 2013; Nairobi in 2015; and Buenos Aires in 2017; and again by the General Council in 2019.

Despite extensive analysis and debate on this issue,¹⁵⁷ WTO members remain divided on whether non-violation or situation complaints should apply to the TRIPS Agreement. Debate therefore addresses not merely the scope and modalities of such disputes, but whether they should be admissible at all within the WTO dispute settlement system.¹⁵⁸ By one view, non-violation complaints are an inherent part of the dispute settlement system for all WTO agreements, as established in the original WTO package of law, and there are adequate safeguards in place to ensure that such disputes are managed in a balanced and fair way. Others argue that the TRIPS Agreement is not a market access agreement and that non-violation disputes in trade law typically relate to denied market access expectations. Concerns are expressed that such disputes may curb members' effective use of policy flexibilities in the implementation of their IP systems; by another view, such constraints would not be experienced. At the time of writing, these differences remained and no proposal on scope and modalities had been considered by the Council.

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 LDCs (Article 66.2). It also allowed LDCs eleven 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. Following requests by LDC members, the TRIPS Council has extended the transition period twice, first in 2005 and then in 2013, until July 2021 for all LDCs. Separately, pursuant to the directions given to it in the 2001 Doha Declaration, the TRIPS Council had already, in 2002, extended the period for LDCs to implement and enforce TRIPS provisions specifically relating to patents and test data with respect to pharmaceutical products to January 2016. In 2015 it extended this transition period again, this time until January 2033.¹⁵⁹

When the TRIPS Council agreed in 2005 to the first 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 decision¹⁶⁰ recognized the special needs and requirements of LDC members, the economic, financial and administrative constraints that they continue to face, and their

¹⁵⁷ See the Summary Note by the Secretariat, [IP/C/W/349/Rev.2](#).

¹⁵⁸ For recent member communications summarizing positions and offering proposals on this subject, see [IP/C/W/385/Rev.1](#) and Add.1-3 and [IP/C/W/599](#).

¹⁵⁹ See Module I, section D1(c) and Module X, section B6 for additional details regarding the extension of these transition periods and the General Council's waiver of obligations under Article 70.8 and 70.9.

¹⁶⁰ [IP/C/40](#).

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 IP 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-2013, nine 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 focused 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 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 include the United Nations Conference on Trade and Development (UNCTAD) and the WHO, the latter on TRIPS and public health issues.

The WTO Secretariat, at the request of the LDC Group, has held several workshops to support the identification of priority needs and the alignment of resources. Other wider initiatives, such as Aid-for-Trade and the Enhanced Integrated Framework, also provide avenues for coordinated efforts to respond to the individual priority needs identified by LDCs that relate specifically to the TRIPS Agreement.¹⁶¹

In 2013, the Swedish International Development Cooperation Agency financed a factual overview on technical and financial cooperation related to the TRIPS Agreement,¹⁶² drawing upon information provided to the TRIPS Council and other WTO bodies by members and intergovernmental cooperation partners. The report sought to promote efforts to match LDC priority needs with available

¹⁶¹ For further information, see [IP/C/W/544](#).

¹⁶² Saana Consulting, ‘Factual Overview on Technical & Financial Cooperation for LDCs Related to the TRIPS Agreement: Identifying and Responding to Individual Priority Needs of LDCs’ (May 2013), prepared for the Swedish International Development Cooperation Agency, available at: www.wto.org/english/tratop_e/trips_e/lcd_overview_08.05.2013_full.pdf.

programmes and providers of technical and financial assistance, thereby supporting LDC efforts to implement the TRIPS Agreement in a manner that is responsive to domestic policy objectives.

5 *TRIPS and transfer of technology*

Developing countries, in particular, see technology transfer as part of the bargain in which they have agreed to protect IPRs. 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 IP, including developmental and technological objectives. Article 7 ('Objectives') states that the protection and enforcement of IPRs 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 D3, Article 66.2 of the TRIPS Agreement 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 66.2.¹⁶³ The Council duly adopted a decision setting up this mechanism in February 2003.¹⁶⁴ It details the information developed countries are to supply for the review by the Council at its annual end-of-year meeting. Since then, the LDC Group has proposed that the TRIPS Council deliberate the meaning of 'incentives to enterprises and institutions' and further specify the format and content of developed country reports to differentiate activities reported under Article 66.2 from those reported under Article 67.¹⁶⁵ More details on these monitoring mechanisms and the resulting documentation are provided in Appendix 1, section D.

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,¹⁶⁶ and the ensuing 2003 and 2005 decisions on TRIPS and public health.¹⁶⁷

Since 2008, the WTO Secretariat has held regular workshops to promote members' understanding of the operation of Article 66.2 and further dialogue between LDC beneficiaries and donors.

¹⁶³ [WT/MIN\(01\)/17](#), para. 11.2.

¹⁶⁴ [IP/C/28](#).

¹⁶⁵ See, e.g. [IP/C/W/561](#) and [IP/C/W/640](#).

¹⁶⁶ [WT/MIN\(01\)/DEC/2](#), reproduced in Annex 6 to this Guide.

¹⁶⁷ [WT/L/540](#) and Corr.1 and [WT/L/641](#), reproduced in Annex 7 and Annex 8, respectively, to this Guide.

6 Electronic commerce and TRIPS

The Ministerial Conference adopted a 'Declaration on Global Electronic Commerce' in 1998.¹⁶⁸ 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 General Council subsequently established a Work Programme on Electronic Commerce¹⁶⁹ 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 the view of members that the novelty and complexity of the IP 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 Add.1. No specific conclusions or follow-up actions emerged from these discussions.

Electronic commerce discussions were reinvigorated in the TRIPS Council in 2016. Although members disagree as to whether electronic commerce should again be a standing item on the Council's agenda, substantive discussions have occurred on an *ad hoc* basis on a range of issues that relate to digital trade in IP protected goods and the IP protection of technology that enables electronic commerce. These topics include copyright rules in the digital environment, electronic signatures, the role and opportunities of electronic commerce in developing countries and for micro, small and

¹⁶⁸ [WT/MIN\(98\)/DEC/2](#).

¹⁶⁹ [WT/L/274](#).

medium enterprises (MSMEs), and member practices enforcing IP rights in the digital environment. Although the discussions in the TRIPS Council have thus far been exploratory in nature, seventy-six members agreed in early 2019 to commence WTO negotiations on trade-related aspects of electronic commerce, ‘build[ing] on existing WTO agreements and frameworks with the participation of as many WTO members as possible’.¹⁷⁰

C Climate change and TRIPS

IP rights, and patents in particular – specifically how they are granted, regulated and exercised under the TRIPS Agreement – are relevant to how technologies related to climate change are developed and transferred around the world. International negotiations and policy debate on climate change have touched on several issues concerning IP in general (see section G5 below), and the TRIPS Agreement in particular. WTO members have also discussed this subject in TRIPS Council meetings. The TRIPS Agreement is part of the international IP system that aims to contribute to promoting technological innovation and its transfer and dissemination.

Ecuador first brought this subject to the TRIPS Council in March 2013, when it submitted a document entitled ‘Contribution of IP to Facilitating the Transfer of Environmentally Rational Technology’ ([IP/C/W/585](#)). The issue was then discussed in a series of TRIPS Council meetings, with full reports of the extensive exchanges recorded in the Council minutes. These records are readily accessible at www.wto.org/climatechange and through the e-TRIPS Gateway, e-trips.wto.org.

Green technology and climate adaptation and mitigation technologies have increasingly been covered in members' reports on technology transfer mechanisms under the Article 66.2 reporting process (see Appendix 1, section D1). The WTO has also covered climate change in some of its flagship technical assistance activities, as well as undertaking specialist training programs on request of members (with details available at the above website). A Secretariat paper provides a factual overview of the TRIPS provisions relevant to the climate change issue.¹⁷¹

D Innovation

A balanced and effective IP system is recognized as an integral element of the policy framework that supports innovation. The role of IP rights in enabling and promoting innovation, and in facilitating the dissemination of the outcomes of innovative activities, is widely debated internationally and domestically, and is the subject of active policy consideration in many countries. The TRIPS Agreement recognizes the significance of the IP system for innovation, providing (in Article 7) that the ‘protection and enforcement of intellectual property rights should contribute to the promotion of

¹⁷⁰ [WT/L/1056](#).

¹⁷¹ www.wto.org/english/tratop_e/trips_e/trips_and_climate_paper_e.pdf.

technological innovation and to the transfer and dissemination of technology'. The United Nation's (UN) 2030 Agenda for Sustainable Development, agreed in 2015, includes innovation as a goal in itself (as Target 9.5); and innovation and the diffusion of innovative technologies are also elements of achieving other Sustainable Development Goals (SDGs), such as those concerning food, climate, health, energy, sanitation, and environmental protection.

Recent years have seen a series of discussions in the WTO TRIPS Council on different aspects of the interplay between the IP system and the policy and practice of innovation, which have covered a wide range of national experiences in developing and applying innovation policy and the related use of the IP system as a means to promote such policies. These discussions (fully reported in the Council's minutes, and available for consultation through the e-TRIPS Gateway) have covered diverse aspects of the interplay between IP and innovation, including:

- IP and innovation in general;¹⁷²
- MSMEs;¹⁷³
- cost-effective innovation;¹⁷⁴
- contribution of IP to facilitate the transfer of environmentally rational technology;¹⁷⁵
- university technology partnerships;¹⁷⁶
- innovation incubators;¹⁷⁷
- promoting awareness: case studies;¹⁷⁸
- women and innovation;¹⁷⁹
- the role of IP in financing innovation;¹⁸⁰
- entrepreneurialism and new technologies;¹⁸¹
- education and diffusion;¹⁸²
- sustainable resource and low emission technology strategies;¹⁸³
- regional innovation models;¹⁸⁴ and
- inclusive innovation and MSME collaboration,¹⁸⁵ growth and trade.¹⁸⁶

¹⁷² [IP/C/M/71](#).

¹⁷³ [IP/C/M/72](#).

¹⁷⁴ [IP/C/M/73/Add.1](#).

¹⁷⁵ [IP/C/M/74/Add.1](#).

¹⁷⁶ [IP/C/M/75/Add.1](#).

¹⁷⁷ [IP/C/M/76/Add.1](#).

¹⁷⁸ [IP/C/M/77/Add.1](#).

¹⁷⁹ [IP/C/M/78/Add.1](#).

¹⁸⁰ [IP/C/M/79/Add.1](#).

¹⁸¹ [IP/C/M/80/Add.1](#).

¹⁸² [IP/C/M/81/Add.1](#).

¹⁸³ [IP/C/M/82/Add.1](#).

¹⁸⁴ [IP/C/M/83/Add.1](#).

¹⁸⁵ [IP/C/M/85/Add.1](#). See also [IP/C/W/622](#) and [IP/C/W/625](#).

¹⁸⁶ See, e.g. [IP/C/M/87/Add.1](#) and Corr.1 and [IP/C/M/90/Add.1](#).

E IP and the public interest

Since its negotiation and conclusion, the TRIPS Agreement has been considered in relation to a number of public policy issues, reflecting the objective of IP protection set out in Article 7, including the advancement of social and economic welfare. A number of delegations have tabled agenda items in the TRIPS Council under the theme of 'IP and the public interest', including:

- compulsory licensing, particularly of patented medicines;¹⁸⁷
- the regulatory review exception to exclusive patent rights;¹⁸⁸
- the application of competition policy, particularly in relation to the pharmaceutical sector;¹⁸⁹
- research and development costs and pricing of medicines and health technologies;¹⁹⁰ and
- the 'three-step test' for copyright limitations and exceptions, as provided in Article 13 of the TRIPS Agreement.¹⁹¹

These discussions are fully reported in the Council's minutes, and are available for consultation through the e-TRIPS Gateway.

F Competition policy

Within the WTO, the TRIPS Council has from time to time considered the policy significance of competition policy safeguards, and the potential contribution of measures such as those envisaged under Article 40.¹⁹² The TRIPS Council has also discussed the possible role of measures under Article 40 to address concerns about access to key biotechnologies,¹⁹³ and 'anti-competitive practices which threatened food sovereignty of people in developing countries.'¹⁹⁴ Most recently, the Council discussed competition policy during meetings held in 2018 and 2019 in the context of an agenda item entitled 'IP and the Public Interest'¹⁹⁵ and related member submissions.¹⁹⁶ The discussion covered a range of potential areas of interaction among competition policy, the IP system and public health, and included accounts by some members of their domestic experience. At the same time, other members

¹⁸⁷ [IP/C/M/86/Add.1](#) and Rev.1 and [IP/C/M/87/Add.1](#) and Corr.1. See also Module V, section B3(b) and Module X.

¹⁸⁸ [IP/C/M/88/Add.1](#). See also Module V, section B3(a) above.

¹⁸⁹ [IP/C/M/89/Add.1](#), [IP/C/M/90/Add.1](#) and [IP/C/M/91/Add.1](#). See also section G4 below.

¹⁹⁰ [IP/C/M/93/Add.1](#).

¹⁹¹ [IP/C/M/94/Add.1](#). See also Module II, section B3 above.

¹⁹² See related discussion in Module VII, section D above.

¹⁹³ [IP/C/M/28](#).

¹⁹⁴ [IP/C/M/64](#).

¹⁹⁵ See [IP/C/M/89](#), [IP/C/M/90](#) and [IP/C/M/91](#) and their addenda and corrigenda. See also WTO News Item, 'Members Debate IP's Societal Value, Role with Competition Policy to Promote Public Health', 5-6 June 2018, available at: www.wto.org/english/news_e/news18_e/trip_08jun18_e.htm; and WTO News Item, 'Members Debate Way Forward on Non-Violation Complaints at TRIPS Council', 18 October 2019, available at: www.wto.org/english/news_e/news19_e/trip_18oct19_e.htm.

¹⁹⁶ See [IP/C/W/643](#) and [IP/C/W/649](#) and their addenda.

cautioned against overly broad interpretations of provisions in the TRIPS Agreement and the risk of upsetting the balance of interests established in the Agreement.¹⁹⁷

In addition to the TRIPS Council, the Working Group on the Interaction between Trade and Competition Policy¹⁹⁸ undertook an early work on the interplay between IP and competition policy during which a number of members reported on their domestic experiences. Information on how individual members have applied competition policy to the exercise of IPRs can also be found in the trade policy reviews regularly undertaken pursuant to the Trade Policy Review Mechanism in Annex 3 of the WTO Agreement, and in accession negotiation documents, including Working Party reports.¹⁹⁹

At the level of individual WTO members, the application of competition law *vis-à-vis* IP has, in many cases, been the subject of relevant guidelines and advocacy initiatives in addition to enforcement proceedings and/or policy discussion and debate. While partial policy convergence has been observed across various jurisdictions, these issues are not settled across all jurisdictions; nor are they necessarily addressed in similar ways.²⁰⁰

G TRIPS in other multilateral policy processes

This Guide focuses on the TRIPS Agreement as one of the legal agreements within the WTO 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 the WTO that 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.

¹⁹⁷ See also Robert D. Anderson, Anna Caroline Müller and Antony Taubman, 'The WTO TRIPS Agreement as a Platform for the Application of Competition Policy in the Contemporary Knowledge-Based Economy: Origins and Prospects', WTO Staff Working Paper (forthcoming), to be available at: www.wto.org/workingpapers.

¹⁹⁸ The Working Group was established as a result of the 1996 Ministerial Conference in Singapore and has been inactive since 2004. See also Robert D. Anderson, William E. Kovacic, Anna Caroline Müller and Nadezhda Sporysheva, 'Competition Policy, Trade and the Global Economy: Existing WTO Elements, Commitments in Regional Trade Agreements, Current Challenges and Issues for Reflection', WTO Staff Working Paper ERSD-2018-12 of 31 October 2018, available at: www.wto.org/english/res_e/reser_e/ersd201812_e.pdf.

¹⁹⁹ See Anderson, Müller, and Taubman, fn 197 above.

²⁰⁰ See Robert D. Anderson, Jianning Chen, Anna Caroline Müller, Daria Novozhilina, Philippe Pelletier, Nivedita Sen and Nadezhda Sporysheva, 'Competition Agency Guidelines and Policy Initiatives Regarding the Application of Competition Law vis-à-vis Intellectual Property: An Analysis of Jurisdictional Approaches and Emerging Directions', WTO Staff Working Paper ERSD-2018-02 of 6 March 2018, available at: www.wto.org/english/res_e/reser_e/ersd201802_e.pdf; and related discussion in Module VII, section D above.

This section provides an informal guide only, to help understand the wider context of the TRIPS Agreement and to provide general orientation. It does not attempt to address the substantive issues raised. This section should not, therefore, be relied on as a source of information about the legal or policy issues, nor about the activities and policies of other international organizations. Detailed information is available directly from the organizations concerned.

1 *TRIPS and human rights*

The principal mechanism within the UN system dealing with human rights is the Human Rights Council, an intergovernmental 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;
- the rights of indigenous peoples;
- the right to benefit from scientific progress and its applications; and
- the right to development.

In 2001, the High Commissioner for Human Rights issued a report on the impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights on Human Rights.²⁰¹ This report discussed several aspects of the TRIPS Agreement relating to human rights, with a particular emphasis on the right to health.

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, the rights of indigenous peoples, and in the field of cultural policy have discussed various aspects of the TRIPS Agreement. A 2016 Council resolution on Promoting the right of everyone to the enjoyment of the highest attainable standard of physical and mental health through enhancing capacity-building in public health also referenced the TRIPS Agreement.²⁰²

²⁰¹ UN document E/CN.4/Sub.2/2001/13.

²⁰² UN document A/HRC/RES/32/16.

The United Nations Committee on Economic, Social and Cultural Rights (CESCR) adopted in 2005 a General Comment on Article 15.1(c) of the International Covenant on Economic, Social and Cultural Rights (ICESCR) that concerns an author's right to benefit from the protection of moral and material interests resulting from his or her creative work.²⁰³ 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 IPRs under national legislation or international agreements, including the TRIPS Agreement.

The UN Declaration on the Rights of Indigenous Peoples²⁰⁴ refers to IP in the following terms: 'Indigenous peoples have ... the right to maintain, control, protect and develop their intellectual property over [their] cultural heritage, traditional knowledge, and traditional cultural expressions.' (Article 31).

Other organizations dealing with human rights issues have also considered the TRIPS Agreement: for instance, the United Nations Educational, Scientific and Cultural Organization (UNESCO) Universal Declaration on Human Rights and Bioethics cites both the TRIPS Agreement and the Doha Declaration in its Preamble.

2 *The TRIPS Agreement and public health beyond the WTO*

While emphasizing the scope in the TRIPS Agreement available for members to tailor their domestic implementation with a view to promoting access to medicines, the Doha Declaration stresses the need for the Agreement to be 'part of the wider national and international action to address these problems'. It is generally accepted that there is a need for a broad-based approach to access to medicines, which should include dimensions such as innovation, access and funding. Other policies affecting access to medicines that have regularly been referred to include (i) transparent, competitive and non-discriminatory procurement procedures and practices; (ii) effective competition policies; (iii) the need to ensure the safety, quality and efficacy of medicines; (iv) the elimination of tariffs and taxes; and (v) the need to have a sound health care infrastructure in place. It has also been emphasized that alternative funding mechanisms, donations, partnership programmes and licensing agreements, as well as the increased application of tiered-pricing schemes by pharmaceutical companies have contributed to a positive change regarding access to medicines.

The issue of access to medicines is influenced by a number of key players intervening at different levels ranging from discussions, norm-setting and jurisprudence at the international level to action taken by civil society and concrete decisions adopted by the pharmaceutical industry. Coherence, cooperation and dialogue are indispensable at all levels in order to find effective responses to public health challenges, and to ensure that the IP regime is balanced, fair and responsive to public health needs in the manner envisaged in the Doha Declaration.

²⁰³ UN document E/C.12/GC/17.

²⁰⁴ UN document A/RES/61/295.

Consequently, the TRIPS Agreement itself and the Doha Declaration have been extensively analysed and debated in forums beyond the WTO. Foremost amongst these is the WHO, which considers 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 are central in the work of the WHO on public health and IP issues. Particular processes include:

- The Commission on Intellectual Property Rights, Innovation and Public Health which was established by WHO member States in 2003 to examine the interface between IPRs, innovation and public health. In its 2006 report, the Commission extensively discussed the TRIPS Agreement and the Doha Declaration and made 60 recommendations aimed at fostering innovation and improving access to medicines. Among other things, it recognized the important role of IPRs to stimulate innovation of pharmaceutical products for which there are profitable markets, while expressing concerns about the costs associated with patents and the impact on access in resource-poor settings.²⁰⁵
- The Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (GSPOA) which was adopted by the World Health Assembly (WHA) 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, 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'.²⁰⁶

This strategy refers to the TRIPS Agreement in several areas, including on the transfer of health-related technology, the application and management of IP 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.

²⁰⁵ Available at: www.who.int/intellectualproperty/report/en.

²⁰⁶ World Health Organization, *Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property* (Geneva 2011), available at: www.who.int/phi/publications/Global_Strategy_Plan_Action.pdf?ua=1.

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. Experts evaluated and reviewed the GSPOA. Their recommendations were published in a 2017 report,²⁰⁷ and were the subject of a 2018 WHA decision.²⁰⁸ In 2019, the WHO Secretariat presented a comprehensive Road Map for Access to Medicines, Vaccines and other Health Products.²⁰⁹ It sets out the WHO's work plan in this area for the period 2019 to 2023 to implement the GSPOA and other strategic documents.

Based on the WIPO Development Agenda recommendations that were adopted by the WIPO General Assembly in 2007,²¹⁰ work at WIPO covers a number of areas that are directly relevant for public health. For example, in consideration of issues related to innovation and access in the pharmaceutical sector and the link with patents at WIPO's Standing Committee on the Law of Patents (SCP),²¹¹ the TRIPS Agreement and the Doha Declaration have played an important role.²¹²

The TRIPS Agreement has also been referenced in the UN SDGs, specifically SDG 3, to 'ensure healthy lives and promote well-being for all at all ages'.²¹³ A High-Level Panel on Innovation and Access to Health Technologies, convened by the then UN Secretary-General, released a report in September 2016 that sought to 'review and assess proposals and recommend solutions for remedying policy incoherence between the justifiable rights of inventors, international human rights law, trade rules and public health in the context of health technologies'.²¹⁴ The report has been the subject of debate during TRIPS Council meetings,²¹⁵ as well as at the WHO and in the SCP.

The broader issues have fostered cooperation between the three intergovernmental organizations with key responsibilities in this area, namely the WHO, WIPO and the WTO. This cooperation was initially framed by the Doha Declaration and has now led to an intensified process of trilateral cooperation, which also includes the implementation of the WHO's GSPOA, WIPO's Development Agenda, and the UN SDGs.

²⁰⁷ World Health Organization, 'Overall Programme Review of the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property – Report of the Review Panel' (November 2017), available at: www.who.int/medicines/areas/policy/overall-programme-review-global-strategy-phi/en.

²⁰⁸ WHO document WHA71(9), available at: [apps.who.int/gb/ebwha/pdf_files/WHA71/A71\(9\)-en.pdf](https://apps.who.int/gb/ebwha/pdf_files/WHA71/A71(9)-en.pdf).

²⁰⁹ World Health Organization, *Road Map for Access to Medicines, Vaccines and other Health Products – 2019–2023 – Comprehensive Support for Access to Medicines, Vaccines And Other Health Products* (Geneva 2019), available at: apps.who.int/iris/handle/10665/330145.

²¹⁰ www.wipo.int/ip-development/en/agenda.

²¹¹ For an overview of health-related topics and issues discussed at the SCP, see www.wipo.int/patents/en/topics/public_health.html.

²¹² See, e.g. Study on the Role of Patent Systems in Promoting Innovative Medicines, and in Fostering the Technology Transfer Necessary to Make Generic and Patented Medicines Available in Developing Countries and Least Developed Countries, WIPO Document [SCP/21/8](#) of 10 October 2014; Constraints Faced by Developing Countries and Least Developed Countries in Making Full Use of Patent Flexibilities and Their Impact on Access to Affordable Especially Essential Medicines for Public Health Purposes in those Countries, WIPO Document [SCP/26/5](#) of 2 June 2017 and Supplement in WIPO Document [SCP/27/6](#) of 20 November 2017.

²¹³ See, in particular, Target 3.B which refers to the Doha Declaration. Available at: sustainabledevelopment.un.org/sdg3.

²¹⁴ *Report of the United Nations Secretary-General's High-Level Panel on Access to Medicines: Promoting Innovation and Access to Health Technologies* (September 2016), available at: www.unsgaccessmeds.org/final-report.

²¹⁵ See, in particular, TRIPS Council meetings of 8–9 November 2016, [IP/C/M/83](#) and Add.1, and TRIPS Council meetings of 1–2 March 2017, WTO documents [IP/C/M/85](#) and Add.1.

This partnership between the three organizations builds on the complementary roles of each organization and takes into account the different nature of their respective mandates and priorities. It has manifested in several concrete outcomes, including a series of symposia (Box XI.1 below), workshops, and a joint study entitled *Promoting Access to Medical Technologies and Innovation: Intersections between Public Health, Intellectual Property and Trade* (Trilateral Study).²¹⁶

| BOX XI.1 WHO-WIPO-WTO TECHNICAL SYMPOSIA | |
|--|---|
| 2010 | Access to Medicines: Pricing and Procurement Practices |
| 2011 | Access to Medicines: Patent Information and Freedom to Operate |
| 2013 | Medical Innovation – Changing Business Models |
| 2014 | Innovation and Access to Medical Technologies: Challenges for Middle-Income Countries |
| 2015 | Public Health, Intellectual Property and TRIPS at 20: Innovation and Access to Medicines: Learning from the Past, Illuminating the Future |
| 2016 | Antimicrobial Resistance: How to Foster Innovation, Access and Appropriate Use of Antibiotics? |
| 2018 | Sustainable Development Goals: Innovative Technologies to Promote Healthy Lives and Well-Being |
| 2019 | Cutting-edge Health Technologies: Opportunities and Challenges |

Further, the WTO, in collaboration with the WHO and WIPO, has offered annual workshops for members since 2014 on ‘Trade and Public Health’ with the aim of building members’ capacity to analyse policy issues at the intersection between trade, intellectual property, and public health. The workshops, which are based on earlier workshops on ‘IP and Public Health’ organized by the WTO since 2005, follow the approach of the Trilateral Study, and review multilateral trade agreements in the broader context of innovation and access to medical technologies.²¹⁷

3 TRIPS and development issues

The relationship between IP systems and economic, social and cultural development has been a cross-cutting question, analysed and debated throughout the UN 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 LDCs in particular.

²¹⁶ WHO, WIPO, and WTO, *Promoting Access to Medical Technologies and Innovation: Intersections between Public Health, Intellectual Property and Trade* (2012), available at: www.wto.org/trilateralstudy2013.

²¹⁷ More information on the trilateral cooperation is available at: www.wto.org/who-wipo-wto.

The UN SDGs establish a framework for a broad-based approach to multilateral cooperation for development. Fulfilment of these goals will require innovation and the effective application of the fruits of innovation in many areas of technology, notably energy, health, and agriculture. A number of SDGs include sectoral targets that are also, effectively, targets for technological innovation – for instance, 2.A on agricultural research; 3.B on medicines R&D; 7.3, 7.A and 7.B on energy technology; 12.A on environmentally sound technology; and 14.A on marine technology. And Target 9.5 expressly frames ‘encouraging innovation’ as such, in the context of both scientific research and upgrading industrial technological capacity (see section D in this module on Innovation). SDG 3, on public health, specifically addresses the role of the TRIPS Agreement in the following terms:

Support the research and development of vaccines and medicines for the communicable and non-communicable diseases that primarily affect developing countries, provide access to affordable essential medicines and vaccines, in accordance with the Doha Declaration on the TRIPS Agreement and Public Health, which affirms the right of developing countries to use to the full the provisions in the Agreement on Trade-Related Aspects of Intellectual Property Rights regarding flexibilities to protect public health, and, in particular, provide access to medicines for all.²¹⁸

The development implications of the TRIPS Agreement have also 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 IP 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.

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

²¹⁸ Target 3.B, available at: sustainabledevelopment.un.org/sdg3.

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 UN 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*²¹⁹

The interplay between competition policy and the IP system has been the subject of recent policy debate on a range of issues, notably IP licensing practices that potentially restrain competition; settlements between parties in patent infringement cases (particularly when bearing on market entry of generic pharmaceuticals); what are termed ‘patent thickets’ (clusters of numerous patents around the same product area); the scope of refusals to license standard essential patents on fair, reasonable and non-discriminatory (FRAND) terms, notably in the information and communication technology sector;²²⁰ and the relevance of competition law principles to the acquisition of IPRs, particularly in the context of mergers and acquisitions.

The application of competition policy provisions in the area of IP is discussed in a number of multilateral fora outside the WTO, including WIPO, UNCTAD and the OECD. Recommendation 23 of the WIPO Development Agenda concerns how ‘to better promote pro-competitive intellectual property licensing practices, particularly with a view to fostering creativity, innovation and the transfer and dissemination of technology to interested countries, in particular developing countries and LDCs’ and Recommendation 32 concerns an exchange in WIPO of ‘national and regional experiences and information on the links between IPRs and competition policies.’ This has led to a range of studies published by WIPO, including on IP, joint R&D and competition; on the antitrust dimension of IP licensing agreements in support of technology transfer; on patent pools and antitrust; on copyright, competition and development; on technology transfer agreements and antitrust; on refusals to license IP rights; on the anti-competitive enforcement of IP rights; on compulsory licenses to address anti-competitive uses of IP rights; on measures to address the interface between antitrust and franchising agreements; on the effects of IP rights as a barrier to entry; on the interaction of agencies dealing with IP and competition law; and on the interface between exhaustion of IP rights and competition law (see www.wipo.int/ip-competition).

²¹⁹ For an overview of the international dimension of competition policy, see Anderson, Kovacic, et al., fn 198 above, and Anderson, Chen, et al. fn 200 above.

²²⁰ See Xiaoping Wu, ‘Interplay between Patents and Standards in the Information and Communication Technology (ICT) Sector and its Relevance to the Implementation of the WTO Agreements’, WTO Working Paper ERSD-2017-08 of 7 April 2017, available at: www.wto.org/english/res_e/reser_e/ersd201708_e.htm. See also Robert D. Anderson, Anna Caroline Müller and Antony Taubman, ‘The WTO TRIPS Agreement as a Platform for the Application of Competition Policy in the Contemporary Knowledge-Based Economy: Origins and Prospects’, WTO Staff Working Paper (forthcoming), to be available at: www.wto.org/workingpapers.

UNCTAD work on Competition and Consumer Protection Laws and Policies has addressed various aspects of IP systems, including preparing studies on competition policy and the exercise of IP rights (<https://unctad.org/en/Pages/DIAE/Intellectual-Property.aspx>) and on the interplay between competition policy, IP, transfer of technology and access to medicines. Relevant discussions take place annually in the UNCTAD Intergovernmental Group of Experts on Competition Law and Policy.

The OECD Directorate for Financial and Enterprise Affairs programme on competition policy has also addressed a number of issues relating to the licensing of IP rights by, *inter alia*, developing guidelines, including at the annual Global Forum on Competition and at specialist roundtables (e.g. www.oecd.org/daf/competition/licensing-of-ip-rights-and-competition-law.htm), and publishing studies and related background papers (see, e.g. [one.oecd.org/document/DAF/COMP\(2019\)3/en/pdf](http://one.oecd.org/document/DAF/COMP(2019)3/en/pdf)).

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 UN system's designated entity for addressing environmental issues at the global and regional level. Three 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 – first, the IP issues relating to the principles of prior informed consent and equitable sharing of benefits from the use of genetic resources and associated traditional knowledge, within its work programme on access and benefit sharing (a work programme 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. The importance of climate change technologies is underscored in an observation by the UNFCCC Secretariat, that 'developing and transferring technologies to support national action on climate change has been an essential element from the beginning of the UNFCCC process'. The 2015 Paris Agreement, concluded under the aegis of the UNFCCC, sought to strengthen the global response to the threat of climate change by keeping a global temperature rise

in this century to well below 2 degrees Celsius above pre-industrial levels and to pursue efforts to limit the temperature increase even further to 1.5 degrees Celsius. The UNFCCC Technology Mechanism is charged with both policy and practical dimensions of green innovation and technology transfer. The UNFCCC Secretariat observes that 'to achieve the Paris Agreement, technology will play an even more important role in supporting countries to meet the challenge of climate change. The Technology Mechanism will be an important player in facilitating such efforts.' While the Paris Agreement does not directly address IP as such, its provisions on technology development and transfer relate in a practical way to the exercise of IP rights, particularly patents on green technologies.

- WIPO GREEN, an interactive marketplace that connects technology and service providers with those seeking innovative solutions, was established by WIPO in 2013. WIPO GREEN consists of an online database and network that brings together a wide range of players in the green technology innovation value chain, and connects owners of new technologies with individuals or companies who might be looking to commercialize, license or otherwise distribute a green technology. It aims not only to accelerate innovation and diffusion of green technologies, but also contribute to the efforts of developing countries in addressing climate change. It can be accessed at www3.wipo.int/wipogreen.