

Analytical Note SC/DIIP/AN/TRIPS/1 March 2017

Original: English

THE TRIPS AND WTO NEGOTIATIONS:

STAKES FOR AFRICA¹

SUMMARY

This paper discusses the current negotiation issues in the context of the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) and the position the African Group has taken in these negotiations. It proposes forward-looking recommendations for the African Group considering the objective of regional trade integration.²

The focus of discussions on TRIPS issues has been the implementation of the provisions of the Agreement, rather than negotiations on outstanding negotiation issues from the text of the TRIPS itself (in – built agenda) or from the Uruguay Round ("implementation issues"). (Continues in next page)

March 2017 Geneva, Switzerland

This South Centre Analytical Note is produced by the South Centre's Development, Innovation and Intellectual Property Programme (DIIP). The objective of this Analytical Note is to analyse the current negotiation issues in the context of the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) and the position the African Group has taken in these negotiations. It proposes forward-looking recommendations for the African Group considering the objective of regional trade integration. Readers are encouraged to quote or reproduce the contents of this South Centre Analytical Note for their own use, but are requested to grant due acknowledgement to the South Centre and to send a copy of the publication in which such quote or reproduction appears to the South Centre.

The South Centre is an intergovernmental organization of developing countries. It prepares, publishes and distributes information, strategic analyses and recommendations on international economic, social and political matters of concern to the South. The South Centre's output does not necessarily reflect the official positions or views of its Member States or other developing countries.

Electronic copies of this and other South Centre publications may be downloaded without charge from http://www.southcentre.int.

¹ This analytical piece has been produced with the support and collaboration of the African Trade Policy Centre of the United Nations Economic Commission for Africa (UNECA).

² For a more detailed discussion on international intellectual property rules and the implications for Africa, see Syam, N., Munoz Tellez, V. "Innovation and Global Intellectual Property Regulatory Regimes: the Tension between Protection and Access in Africa," Research Paper 67, July 2016, South Centre, Geneva, available at <u>https://www.southcentre.int/research-paper-67-june-2016</u>, Prepared as a background paper for UNECA ARIA Report, 2015.



SOUTH



Analytical Note SC/DIIP/AN/TRIPS/1 March 2017

Original: English

SUMMARY (continued)

African countries are not the main demandeurs of international rules on intellectual property including the WTO TRIPS Agreement.³ They have had limited influence in shaping them. Yet since 1998 African countries have advanced a common agenda on TRIPS issues. The African Group has been at the forefront of TRIPS related work on access to medicines⁴, as well on the use of biodiversity and traditional knowledge as a source of patentable inventions. This is reflected in the African Group and LDC group positions on the review of Article 27.3(b) of the TRIPS Agreement, as well as on the extension of transition periods for LDCs under Article 66.1 not to comply with the TRIPS Agreement. The African Group has also continuously supported for domestic policy space for LDCs in intellectual property by way of the extension of TRIPS transition periods.

The mandate for negotiation of certain pending TRIPS issues is in-built in the text of the TRIPS Agreement itself. Negotiations on other TRIPS issues are the result of decisions of WTO Ministerial Conferences. The WTO Nairobi Ministerial Declaration of 2015 (WT/MIN(15)/DEC, paragraph 31) reaffirmed the strong commitment of all Members to advance negotiations on TRIPS issues under the work programme of the Doha Ministerial Declaration (WT/MIN(01)/DEC/1). The TRIPS issues are referred to in the Doha Ministerial Declaration as TRIPS "implementation issues" paragraph 12, elaborated in paragraphs 18 and 19. The deadlines set for the negotiations for processes in-built in TRIPS, and those set out by the Doha Ministerial Declaration, have lapsed.

Little progress has been achieved in the negotiation on the TRIPS issues that are discussed in this paper. The political high level support that is necessary to move the negotiations forward, is absent. This may be partly explained by priority accorded to core trade issues, including examination of "new issues." It may also be explained by the fact that related discussions are underway in other multilateral fora, i.e. the World Intellectual Property Organization (WIPO), the International Treaty on Plant Genetic Resources on Food and Agriculture (ITPGRFA) and in the conference of parties to the Nagoya Protocol to the Convention on Biological Diversity (CBD).

While related negotiations can complement the negotiation of TRIPS issues in the WTO, they are not an effective substitute for achieving results in the WTO TRIPS context. Other international fora lack an effective dispute settlement mechanism to ensure compliance with the obligations, and there is no certainty that negotiations will be successful in the other fora. The various negotiations should be seen as complementary, and coherence should be sought in the participation of the African Group in the various fora.

The TRIPS negotiation issues discussed in this paper are the following:⁵

³ Out of the 54 African countries, 43 are parties to the WTO TRIPS Agreement, as members of the WTO. Among these, the majority –29- are LDCs. The African countries that are not members of the WTO, and thus not party to the TRIPS Agreement, are Algeria, Comoros, Equatorial Guinea, Eritrea, Ethiopia, Liberia, Libya, Sao Tome and Principe, Somalia, Sudan.

⁴ From 2000-2003, intellectual property and public health was the prominent TRIPS negotiation issue. In the face of pressures to adopt intellectual property obligations that could hinder public health goals, particularly foster access to patented medicines, developing countries sought to reaffirm the TRIPS flexibilities that allow for measures to protect public health. The Declaration on TRIPS and Public Health was adopted in the 2001 Doha Ministerial Conference. It also led to further work that led to the General Council Decision of 30 August 2003 on the Implementation of Paragraph 6 of the Doha Declaration.

⁵ There are other issues in the regular agenda of the Council for TRIPS, not discussed here. These include notification of national legislation implementing the TRIPS Agreement, the annual review of the Paragraph 6 system under the Doha Declaration on TRIPS and Public Health (the Protocol amending the TRIPS)





1) Geographical indications (GIs):

OUTH

- establishment of a multilateral register for wines and spirits (in-built in the text of Article 23.4 of the TRIPS Agreement), and

- extension of the level of protection of GIs provided for in Article 23 to products other than wines and spirits (a TRIPS "implementation" issue under the Doha Ministerial Declaration)

2) Patents and other forms of IPR protection in relation to biodiversity, and the protection of traditional knowledge:

- the relationship between the Convention on Biological Diversity (CBD) and the TRIPS Agreement, focused on introducing an amendment to the TRIPS Agreement to require patent applicants to disclose the source and/or origin of genetic resources or traditional knowledge used in an invention (TRIPS "implementation" issue under the Doha Ministerial Declaration);

- the scope of application of patent law to biotechnological inventions, the effective protection for new plant varieties through patents or a *sui generis* system or a combination of both (in-built in the text of Article 27.3(b) of the TRIPS Agreement).

- the protection of traditional knowledge (TRIPS "implementation" issue under the Doha Ministerial Declaration)

3) The applicability of non-violation and situation complaints to the TRIPS Agreement: Article 64.2 of the TRIPS Agreement established that these types of complaints would not apply with respect to the Agreement for five years after entry into force of the Agreement. The issue is recurrently negotiated each time the moratorium period established by the General Council is close to lapse, requiring a new decision.

agreement currently a waiver until the time ³/₄ of WTO members accept the Protocol), the review of the implementation of the TRIPS Agreement under Article 71.1, the reporting on transfer of technology by developed countries to LDCs in compliance with Article 66.2, technical cooperation -Article 68, selection of observers to the TRIPS Council.





THE TRIPS AND WTO NEGOTIATIONS:

STAKES FOR AFRICA

TABLE OF CONTENTS

I.	THE TRIPS AGREEMENT	5
II.	PATENTS AND PLANT VARIETY PROTECTION IN RELATION TO BIODIVERSITY AND TRADITIONAL KNOWLEDGE	6
	II.1 The Review of Article 27.3b	6
	II.2 Patents on Life Forms	8
	II.3 Plant Variety Protection	10
III.	Geographical Indications	15
IV.	THE EXTENSION OF TRANSITION PERIODS FOR LDCs	19
V.	NON-VIOLATION AND SITUATION COMPLAINTS FOR DISPUTE SETTLEMENT UNDER THE TRIPS AGREEMENT	22
ANNEX 1 - African Group, Taking Forward the Review of Article 27.3(b) of the TRIPS Agreement, WTO document IP/C/W/404, 26 June 2003 27		





I. THE TRIPS AGREEMENT

1. Intellectual property was first included as a negotiation topic in multilateral trade negotiations in the 1986-1994 Uruguay Round of the General Agreement on Tariffs and Trade (GATT 1947). There was substantial opposition from developing countries to introduce intellectual property in the multilateral trade system and its in-built dispute settlement mechanism. The decision to negotiate the round as a Single Undertaking package of agreements ultimately led developing countries to give up domestic space on intellectual property policy in exchange of the perceived gains in trade, specially in agriculture and textiles.

2. The World Intellectual Property Organization (WIPO) was the main multilateral fora in which developing countries were participating to some extent in intellectual property norm-setting. Developed countries strategically shifted focus from WIPO to the WTO in order to obtain greater standards of protection and enforcement. When the TRIPS Agreement came into force in the WTO in 1995, developing countries may have expected that the bilateral pressures from foreign corporations and developed countries would diminish. This has not been the case. A range of new international treaties and bilateral and regional agreements continue the trends of strengthening intellectual property rights, expanding their coverage and facilitating their enforcement. The TRIPS Agreement requires all WTO members to provide minimum standards of protection for intellectual property rights, while allowing countries to further increase protection, provided this is not contrary to the agreement. The WTO principle of non-discrimination – national treatment and most favoured nation (MFN) treatment, also apply with respect to the TRIPS Agreement.

Recommendation

3. African countries should aim to establish intellectual property systems that are best suited to the national and regional context and interests, in line with, but not exceeding, existing international obligations.

4. African countries should resist the intellectual property agendas of developed countries and devise their own strategy. Regional integration in Africa should take precedence over trade agreements with other regions, i.e. Economic Partnership Agreements (EPAs), free trade agreements (FTAs) and bilateral investment agreements (BITs) with other parties. The multiplicity of agreements with external parties makes it difficult for African countries to build a solid policy that can be translated into regional normatives that are suited to the regional context.

5. African countries should work together to build regional capacity on intellectual property management, as opposed to reliance on external technical assistance (i.e. USPTO, EPO, WIPO).



II. PATENTS AND PLANT VARIETY PROTECTION IN RELATION TO BIODIVERSITY AND TRADITIONAL KNOWLEDGE

II.1 The Review of Article 27.3b

African Position

6. Three main issues at the heart of the review are: 1) the extent to which patent protection should be available for plant and animal inventions, 2) what may constitute an "effective *sui generis* system" for plant varieties, and 3) the protection of traditional knowledge and the protection of farmers' rights. The latter has received less attention than the two other issues.

7. The African Group was at the forefront of demanding the review of Article 27.3(b) and in advancing proposals. In 1999, the African Group called for a revision to exclude all living forms from patentability. It also requested to harmonize of the TRIPS Agreement with the CBD, to ensure the protection and promotion of Farmers' Rights as recognized in the FAO International Undertaking on Plant Genetic Resources, while preserving the room existing at the national level to develop specific modalities of protection for traditional knowledge.⁶ The African Group argued that by mandating or enabling the patenting of seeds, plants and genetic and biological materials, Article 27.3(b) is likely to lead to appropriation of the knowledge and resources of indigenous and local communities.⁷

Recommendation

8. The topics that are part of the review of Article 27.3(b) remain highly relevant for African countries and LDCs. Continued discussion of the topics identified should be pursued in the TRIPS Council. African Group has maintained that the purpose of the review of Article 27.3(b) is to amend the article. The minimum outcome to pursue in the review of Article 27.3(b) should be to ensure that the flexibility that is presently available under Article 27.3(b) is not diluted. Opening the text of Article 27.3(b) for negotiation may reduce the flexibilities available, unless African and other developing countries have a consistent and resilient position.

9. African countries should aim for greater alignment among their policies and norms, and negotiation positions. In particular, on the conservation and sustainable use of biodiversity, the protection and promotion of traditional knowledge (i.e. in implementing the CBD, its Nagoya Protocol, the FAO ITPGRFA and in the context of human rights, i.e. the UN Declaration of the Rights of Indigenous Peoples and the working group on the rights of peasants), and the scope of biotechnology patenting, plant variety protection and the protection of geographical indications (i.e. in

⁶ WT/GC/W/302 of 6 August 1999 and IP/C/W/206 of 20 September 2000.

⁷ Ibid.





implementing WTO TRIPS, WIPO negotiations). Periodic meetings among members of various ministries in charge for the various negotiations would be useful to foster coherence.

Current State of Play

10. Article 27 of the TRIPS Agreement refers to patentable subject matter. Article 27.1 obliges Members to "make available" patents for all inventions -whether these are products or processes- and in all fields of technology, if they are new, involve an inventive step and are capable of industrial application. Although "patents" are not defined in the TRIPS Agreement, it is understood that they are a legal title granted by a government/jurisdiction that gives the holder -usually a private party-, the exclusive and enforceable right to prevent others from commercially exploiting the invention. This monopoly is time limited – the TRIPS Agreement sets a minimum 20 year period, and subject to conditions, such as the disclosure of the invention, Article 29 and payment of fees for maintenance. Then after, the invention may be put into practice by anyone capable of doing so based on the information disclosed in the patent application.

11. The TRIPS Agreement does not define the term "invention". It also does not set out criteria for defining what is "new", "inventive step" or "non obviousness" and "capable of industrial application". Hence, the Agreement allows space for legal interpretation. One of the implications is that decisions as to whether the patent is granted or not may vary depending on the jurisdiction (i.e. country) in which the applicant is applying for a patent. Whether the patent is granted or not also depends on the extent to which Members exclude certain subject matter from patentability, even when the patent may be fulfilling the criteria for patentability. The permissible exclusions are outlined in Article 27.2 and 27.3a and 27.3b.

12. Article 27.2 permits ethical exceptions to patentability permitted under Article 27.2. Article 27.3 allows Members to exclude from patentability: "(a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals; (b) 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, Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof."

13. As a consequence of the controversial nature of the Article 27.3 obligations, subparagraph 27.3(b) foresaw a future review process: "the provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement." The language was a result mainly of a compromise between the United States, on the one hand, so that all members would allow for patenting of plants and animals, and the European Communities, on the other, that wanted to maintain an exception to the patentability of plants and animals, as this was prohibited under the European Patent Convention (EPC). Moreover, the European Communities were party to UPOV and preferred this system of plant variety protection as opposed to patents.





However, the compromise language does not refer expressly to UPOV, but to an effective *sui generis* system of plant variety protection, patents, or a combination of both forms of protection. At the time, most developing countries did not allow patents on plant and animals, as remains the case today, and they also were not members of the UPOV system, though today a number have joined, including the recent adhesion of the African Regional Intellectual Property Organization (ARIPO).

14. The TRIPS Council began the review in 1999. However, members disagreed as to what was the purpose of the review. Today the deep divides among members in their views on the review of Article 27.3(b) still remain, both on process and substance.⁸ The objective pursued with the amendment was to reduce the scope of patenting, in particular to exclude life forms from patentability (plants, animals, micro-organisms, their parts and natural processes) as these create a range of concerns. These include, the misappropriation of knowledge and resources of indigenous and local communities, and advancing the goals of conservation and sustainable use of genetic resources.⁹

15. To date there is no result from the review process of Article 27.3(b). Despite that the review of article 27.3(b) is a standard issue in the agenda of all meetings of the TRIPS Council, the number of interventions has been on the decrease.

II.2 Patents on Life Forms

African Position

16. The submissions of the African Group in 1999 and 2003 reiterated a call to amend Article 27.3(b) to prohibit patents on life forms, on the grounds that they are unethical. The proposal was made to modify the requirement to provide for patents on micro-organisms and on non-biological and microbiological processes for the production of plants or animals. One of the arguments is ethical. It was argued that "such patents are contrary to the moral and cultural norms of many societies in Members of the WTO. They make the exception in Article 27.2 for protecting ordre public and morality, which Members that consider patents on life forms to be contrary to the fabric of their society and culture, and to be immoral, and which they would otherwise invoke, meaningless in this regard"¹⁰.

 $^{^{8}}$ A summary of the debates on Article 27.3(b) as of 2006 is provided in WTO Secretariat paper IP/C/W/369/Rev.1. The minutes of the meetings of the regional and special sessions of the TRIPS Council provide a factual account of the discussions. On process, for many developed country members, the purpose is to review the implementation of the article. In general, they seek to work towards stronger obligations. In contrast, for most developing countries, it is understood that the review is to amend the article, not review its implementation.

⁹ See Preparations for the 1999 Ministerial Conference the TRIPS Agreement. Communication From Kenya on behalf of the African Group, 29 July 1999, available at http://www.grain.org/es/article/entries/1861-africa-group-position-on-trips.

¹⁰ African Group, Taking Forward the Review of Article 27.3(b) of the TRIPS Agreement, WTO document IP/C/W/404, 26 June 2003.



SOUTH



Original: English

17. Another argument for the review is on a technical level. The African Group has highlighted incongruences raised by the artificial distinction made between plants and animals (which may be excluded from patentability) and micro-organisms (which may not be excluded); and also between essentially biological processes for the production of plants and animals (which may be excluded) and non- or micro-biological processes (which may not be excluded), noting that these distinctions violate the basic principles of intellectual property law¹¹. Accordingly, the African Group has advanced that "the distinction drawn in Article 27.3(b) for micro-organisms, and for non-biological and microbiological processes for the production of plants or animals, is artificial and unwarranted, and should be removed from the TRIPS Agreement, so that the exception from patentability in paragraph 3(b) covers plants, animals, and micro-organisms, as well as essentially biological processes and the non-biological and microbiological processes for the production of plants or animals, and microbiological processes for the production of plants or animals.

Recommendation

18. For African countries, the optimal choice for balancing access and promotion of biotechnology is to interpret as narrowly as possible the obligations under Article 27.3(b) and overall the obligations in Section 5 of the Agreement. To build greater capacity in biotechnology and plant breeding, African countries would do well to pool capacities and resources – human, financial, technology and infrastructure- at the regional level. Increasing patent protection for biotechnological inventions would have limited impact prior to building domestic capacity, as most protected inventions would be foreign thus increasing the cost of access and research. Ethical and moral concerns should also be considered.

Current State of Play

19. In 2010, Bolivia proposed to amend article 27.3(b) to prohibit the patenting of all life forms, protect innovations of indigenous and local farming communities and their farming practices, prevent anti-competitive practices, protect the rights of indigenous communities and prevent any intellectual property claims over traditional knowledge.¹³ The proposal has not been seriously considered so far in the TRIPS Council discussions.

 $^{^{11}}$ African Group, Communication from Mauritius on behalf of the African Group, WTO document IP/C/W/206, 20 September 2000.

¹² African Group, Taking Forward the Review of Article 27.3(b) of the TRIPS Agreement, WTO document IP/C/W/404, 26 June 2003.

 $^{^{13}}$ Review of Article 27.3(B) of TRIPS Agreement, Communication from Bolivia, IP/C/W/545, February 2010; see also IP/C/W/554, also 2011.



Analytical Note SC/DIIP/AN/TRIPS/1 March 2017

Original: English

II.3 Plant Variety Protection

SOUTH

African Position

20. In early submissions on the review of Article 27.3(b), the African Group and others argued on the scope of plant variety protection required. The position was unified around the African Union (AU) Model Law on the Protection of the Rights of Local Communities, Farmers and Breeders and for the Regulation of Access to Biological Resources.¹⁴ Extensive foreign pressure has ensued not to implement the law nationally. The African Group submission in 2003 advanced that several understandings should be agreed internationally, as follows:

"Members have the right and the freedom to determine and adopt appropriate regimes in satisfying the requirement to protect plant varieties by effective *sui generis* systems. In this regard, and for purposes of illustration, such regimes may draw upon the International Treaty on Plant Genetic Resources, the Convention on Biological Diversity, the 1978 Act of the Convention of UPOV, and the African Model Legislation on the Protection of the Rights of Local Communities, Farmers and Breeders and the Regulation of Access to Biological Resources. The appropriate and beneficial approach is to have systems of protection which can address the local realities and needs. The "African Model Legislation on the Protection of the Rights of Local Communities, Farmers and Breeders and the Regulation of Access to Biological Resources" is one example of a *sui generis* system, which has been developed to provide appropriate and effective protection for the rights and knowledge of farmers, as well as indigenous peoples and local communities, in a manner that suits the circumstances of Africa and possibly other developing Members.

(b) Regardless of what *sui generis* system that is adopted for protecting plant varieties, non commercial use of plant varieties, and the system of seed saving and exchange as well as selling among farmers, are rights and exceptions that should be ensured as matters of important public policy to, among other things, ensure food security and preserve the integrity of rural or local communities. While the legitimate rights of commercial plant breeders should be protected, these should be balanced against the needs of farmers and local communities, particularly in developing Members. Any *sui generis* system should enable Members to retain their right to adopt and develop measures that encourage and promote the traditions of their farming communities and indigenous peoples in innovating and developing new plant varieties and enhancing biological diversity.¹⁵

¹⁴ The AU Model Law was endorsed in Ouagadougou, Burkina Faso, in 1998.

 $^{^{15}}$ African Group, Taking Forward the Review of Article 27.3(b) of the TRIPS Agreement, WTO document IP/C/W/404, 26 June 2003.





Analytical Note SC/DIIP/AN/TRIPS/1 March 2017

Original: English

Recommendation

21. African countries that are LDCs are not required to provide any form of intellectual property protection to new plant varieties. Other African countries are obliged by the TRIPS Agreement to provide an effective system of protection to new plant varieties. An option most suitable to African countries is to develop a *sui generis* system that recognizes and incentivizes both industrial breeders as well as farmers as breeders and the role of traditional knowledge and practices in plant breeding. The options of making available patents or joining the UPOV 1991 system for the protection of new plant varieties are not suitable to the African context.

Current State of Play

22. The TRIPS Agreement requires in Article 27.3(b), among other things, that Members provide an effective system for the protection of plant varieties, either through patents, or through a *sui generis* system. Prior to the TRIPS Agreement, most developing countries did not provide intellectual property protection for plant varieties. Developing countries have thus been confronted with questions on how to implement this requirement. The options are to create a specific system of plant variety protection tailored to national circumstances, or to follow the model of plant breeders' protection established under the UPOV Convention, or to protect plant varieties through patents.

23. The option of protecting plant varieties through patents is rejected by most developing countries. Joining the UPOV system offers the advantage that it is "readymade". However, it is a system designed with the interests of commercial plant breeders in mind, and does not adequately fit the local needs and realities in developing countries for agricultural innovation and types of farming. Over 90% of the food consumed comes from small farmers, thus farmer seed systems and maintaining their ability to continue with their traditional practices that are supportive of genetic diversity remains vital. UPOV Act of 1991, the only option available to countries that may wish to join, can limit the use of the farmers' privilege to save and exchange seeds. Many developing countries that did not provide protection to plant varieties have joined UPOV. Nonetheless, a few (e.g. India, Malaysia, Thailand) have introduced *sui generis* legislation. This allows them to establish norms that are compatible with both traditional seed systems and modern seed systems. These norms would not be in compliance with the UPOV standards, therefore they have opted not to join the UPOV system.

24. In recent years this issue is not addressed. In part, as it is recognized that the language reflects a careful balance, requiring effective plant variety protection, but leaving it up to members to decide the way to implement it. Unfortunately, many African countries are pressured under bilateral trade agreements to include an obligation to join UPOV. In 2015, the African Intellectual Property Organization (OAPI) joined UPOV. The national implementation is pending. There are real concerns with the UPOV system in regards to plant varieties and the effect on farmers' rights. African countries





should consider the option of designing their own *sui generis* system of plant variety protection.¹⁶

II.4 The Protection of Traditional Knowledge

African Position

25. The African Group in its submissions has noted that through patents, traditional knowledge whether or not associated to genetic resources may be misappropriated, and has argued for solutions within the WTO framework, while taking note of current ongoing work in WIPO (with no results to date). The African Group has particularly suggested that the Council for TRIPS should consider adopting a Decision on Protecting Traditional Knowledge, that should be an integral part of the TRIPS Agreement.¹⁷ The decision is included as Annex 1 of this document.

Recommendation

26. The Doha Ministerial Declaration extended work on TRIPS issues to the protection of traditional knowledge and folklore. The main concern, related to the scope of patents to be made available as a result of the TRIPS Agreement, is that the intellectual property system may allow third parties outside the community to claim as their own, and gain legal protection to exclude others from the use of creations and inventions that are based on traditional knowledge. Indigenous and local communities regulate the access, use and dissemination of traditional knowledge within their local context through customary laws and practices (which may be distinct from national law). But customary law may prove ineffective in ensuring that rights of communities on traditional knowledge are respected or enforced beyond their local context.

27. Developing countries and indigenous and local communities have been pursuing improved protection for traditional knowledge and folklore in a number of multilateral fora. In the Convention on Biological Diversity, countries committed to "respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices." Moreover, the CBD Nagoya Protocol on Access and Benefit Sharing in 2010 created an international system that defines conditions for access, use and commercial utilization of traditional knowledge related to genetic

¹⁶ For suggestions, see Correa. C, *Sui Generis* Plant Variety Protection *System*: An *Alternative* to *UPOV* 91, Apbrebes, 2015. <u>http://www.apbrebes.org/news/new-publication-plant-variety-protection-developing-countries-tool-designing-sui-generis-plant</u>.

¹⁷ African Group, Taking Forward the Review of Article 27.3(b) of the TRIPS Agreement, WTO document IP/C/W/404, 26 June 2003.





resources. There is concern that patents are granted for inventions using genetic resources and/or traditional knowledge when the applicant did not comply with the national access and benefit sharing law. This is considered a form of "misappropriation" of the genetic resources and/or traditional knowledge.

28. The discussion on the CBD-TRIPS issue has continued to take up this element. In recent years, there has been very little discussion on the protection of traditional knowledge in the TRIPS Council. It may be the case that developing countries are expecting outcomes in the WIPO negotiations on the protection of traditional knowledge in the IGC. The WIPO General Assembly, its highest body, will be taking stock of the negotiations in 2017. To date, there is still very strong opposition to the disclosure requirement with regards to genetic resources and/or traditional knowledge by a few developed countries, namely the United States, Japan and Korea, as is also the case in the WTO.

II.5 TRIPS and CBD Relationship

African Position

29. The African Group is one of the main demandeurs on the issue of creating a mutually supportive relationship between the TRIPS Agreement and the Convention on Biological Diversity (CBD). The African Group has maintained the position that "both the TRIPS Agreement and the Convention on Biological Diversity as well as the International Treaty on Plant Genetic Resources should be implemented in a mutually supportive and consistent manner. In this regard, Members retain the right to require, within their domestic laws, the disclosure of sources of any biological material that constitutes some input in the inventions claimed, and proof of benefit sharing."¹⁸ Accordingly, the African Group is a co-sponsor of the main proposal on the disclosure requirement, which proposes to amend the TRIPS agreement to require all patent applicants to disclose the source/origin of the genetic resource and/or traditional knowledge used in the invention¹⁹. The African Group is advancing a similar proposal in the World Intellectual Property Organization (WIPO) Committee on Intellectual Property, Genetic Resources and Traditional knowledge (IGC).

Recommendation

30. The African Group should reiterate its support for the proposal on CBD-TRIPS disclosure requirement ($\frac{TN/C/W/59}{}$) and its negotiation. The African Group is one of the proponents of this submission. The proposal can be raised again in the Trade Negotiations Committee, as it was submitted to this committee. The ongoing work in the WIPO IGC, including a disclosure proposal, may be a factor for the dwindling of efforts

 $^{^{18}}$ African Group, Taking Forward the Review of Article 27.3(b) of the TRIPS Agreement, WTO document IP/C/W/404, 26 June 2003.

¹⁹ WTO documents IP/C/W/474 Add.1-9 and TN/C/W/59.





in the WTO context on this issue. WIPO will consider the status of negotiation in September 2017.

31. The proposal on disclosure (TN/C/W/59) should be disseminated more widely at regional and national levels, and national and regional patent offices should be pressurized to implement the disclosure requirement.

32. We suggest that the African Group includes the TRIPS implementation issues – particularly the relationship between the CBD and TRIPS – as post-Nairobi MC-10 priorities, to reactivate consultations at the level of the Director General, and to create the necessary political momentum at regional level in order to reaffirm that these negotiations should be a central part of the post-Nairobi negotiations. The African Group should also coordinate with other developing country groups in this regard, including LDCs that unfortunately did not include TRIPS implementation issues under Doha in their list of post-Nairobi priority issues (WTO document <u>WT/GC/W/717</u>). African LDCs may seek to include in subsequent LDC submissions the CBD-TRIPS implementation issue as a priority.

Current State of Play

33. The work on the relationship between the CBD and TRIPS was formalized in the 2001 Doha Declaration in paragraph 12. In the discussion on the relationship between the TRIPS Agreement and the CBD, developing countries have focused their efforts on the introduction of an obligation to disclose the origin of genetic resources and associated traditional knowledge claimed in patent applications. The first proposals on the subject were made in the context of the review of article 27.3(b). However, the proposals shifted later to the consideration of a possible amendment to article 29 of the TRIPS Agreement, which deals with the general disclosure obligation imposed on patent applicants. The TRIPS Agreement does not contain any provisions to ensure that patent applicants have obtained prior informed consent (PIC) from the countries of origin of the genetic resources and complied with national regimes on access and benefit sharing, as required by the CBD. Several submissions outlined the purposes and possible scope of a disclosure obligation relating to patent claims on genetic resources (IP/C/W/429). A group of developing countries, including the African, Caribbean and Pacific Group of States (ACP Group) and the LDCs Group, submitted in 2006 to the Council for TRIPS a proposal for a new article 29bis (IP/C/W/474 Add.1-9). After the adoption of the CBD Nagoya Protocol, the African Group also joined a new submission by the large group of developing countries that reflects some of the elements of the Protocol (TN/C/W/59). These proposals aim at increasing the transparency of the patent system in order to allow countries to monitor and effectively enforce benefit-sharing obligations. They were a response to the concerns created by many reported cases of "bio-piracy" and misappropriation of genetic resources and traditional knowledge.





- 34. The proposal essentially requires patent applicants to:
 - disclose the country of origin and the specific source of the genetic resources and/or of the traditional knowledge used in the invention;
 - provide evidence of PIC through approval of authorities under the relevant national regime; and
 - provide evidence of fair and equitable benefit sharing under the relevant national regime.

35. The European Union has shown its willingness to partially accept the proposed amendment (disagrees on the trigger for the disclosure obligation, the scope of genetic resources covered – not to include derivatives – and the effect of non-compliance on a patent, disagreeing with the option of revocation). However, it has asked in exchange for the support in the creation of an international register for wines and spirits and the extension of GIs protection. In 2008, in order to advance both TRIPS "implementation issues" – the GI extension and the TRIPS-CBD issue, both strongly rejected by the United States, the group of supporters of TRIPS-CBD (including the African Group) and the GI group led by the European Union, agreed to a "modalities text" that linked outcomes on the two TRIPS issues and requested that these be part of the "single undertaking" negotiations, also including the negotiation on the multilateral register for wines and spirits. Although many countries supported the modalities text, ultimately the negotiations as a whole in the Doha round of negotiations – then the July package – failed to arrive at an agreement.

III. GEOGRAPHICAL INDICATIONS

African Position

36. The African Group is not a core proponent of increasing protection for geographical indications beyond the requirements set out in the TRIPS Agreement. There are some individual countries, however, that have expressed interest in strengthening GI protection at the international level, such as Kenya, but the African Group has remained united in its position. Likewise, there is some divergence among the position of individual African countries as to whether they support or not the extension of GIs, and the type of register for wines and spirits that would be established. In contrast, the African Group has a strong position in support of the relationship between the CBD and TRIPS Agreement in the form of the disclosure requirement.

37. The African Group joined the coalition for "modalities text" linking the two GI issues with the relationship of TRIPS and CBD²⁰, as a political compromise to gather greater support and push the United States to negotiate on all TRIPS issues. The African

 $^{^{\}rm 20}\,WTO$ document TN/C/W/52





Group has a strong position in support of the relationship between the CBD and TRIPS Agreement in the form of the disclosure requirement.

Recommendation

38. The African Group does not have a strong interest in increasing the standards of protection of geographical indications beyond the obligations found in the TRIPS Agreement.

39. The position on geographical indications, particularly on the extension of higher protection currently afforded only to wines and spirits in the TRIPS Agreement, should be informed by an assessment of the benefit-cost analysis. Domestic protection for a geographical indication is a precondition for protection in another WTO member. If a geographical indication protected as such nationally or regionally, its protection can be sought in another WTO member.

40. The extension of higher protection of geographical indications to products beyond wines and spirits may benefit the protection of the few geographical indications of African countries, but may be to the detriment of local producers that use similar names/signs for products or services as those protected by a foreign geographical indication.

41. The identification of products that could benefit from protection of geographical indications in African countries and LDCs is a useful exercise in defining offensive interests in this area. A market analysis, and an assessment with local producers would determine whether these may find it useful to use a GI, and to consider various legal means for their protection. The value of a geographical indication is directly related to its ability to add marketing value to a product. It is considered valuable if the GI for the product can drive a premium price. This does not happen by the protection afforded by the GI. A GI may be a relevant tool to support products for which there is a strong consumer base and potential for expansion, domestic and abroad, that is willing to pay more or prefer the product as opposed to similar or alternative ones, because of the value that the consumer attaches to the products unique characteristics, i.e. geographical area giving specific quality/traits to the product. However, identifying potential local geographical indications is only part of the equation. All foreign geographical indications that comply with the conditions of protection specified in TRIPS Article 22 -23 should be awarded protection. This means that local producers of similar products to those demanding GI protection may be potentially affected by the registration of a foreign GI. Hence, in addition to the analysis of domestic potential GIs, there is a need for analysis of the potential economic cost of recognizing foreign GIs on local producers that may be using the denomination.





42. Only a few studies have been undertaken on the question of protection of GIs in the African context.²¹ One report finds that there are few GIs recognized in Africa, and "the determination of the socio-economic benefits of GI protection in Africa requires detailed country by country and product by product analysis. This means that the actual benefits that will accrue to different African countries will vary, in many cases, significantly." On the question of whether African countries should support the extension of GIs, the paper recommends that "until they have better information and evidence, including a better understanding of the very limited use of the currently existing systems, African countries may be well served to demand more empirical evidence and details regarding the proposed special and differential aspects of the amendment to TRIPS."

Current State of Play

43. The TRIPS Agreement requires the protection of geographical indications. GIs are defined as "indications which identify a good as originating in the territory of a Member, or a region or locality in that territory, where a given quality, reputation or other characteristic of the good is essentially attributable to its geographic origin." When a GI is granted, it gives the holder an exclusive right over the relevant geographical names used to commercialize products of geographical origin.

44. The inclusion of GIs was the result of the demands of European countries, the largest number of producers of GI-protected products, and hence benefitting most from their recognition and increased protection worldwide. European countries have a specific system, different from other forms of IP rights, to designate products linked to a geographical origin and ensure standardization among producers that can use a common GI label that may be useful in the marketing of their products and staying ahead of competition. These products usually already enjoy good reputation and are associated by the consumer to a geographical location. French Champagne and Italian Parma ham are examples of European GIs. The United States, in contrast, is not a supporter of the European type of protection for GIs. As a "new" world country the link between a product and its characteristics to its geographical origin product is less stressed in marketing. The United States protects GIs as trademarks, certification marks or collective marks, and these are not designated specifically as GIs. A significant difference of the two systems is that in the EU-type model, the State takes on a significant role of controlling production standards and other conditions of the producer operating under the GI, as well as in its enforcement. In the United States trademarkbased model, enforcement is the role of the trademark holder in courts.

45. These two main divergences led to the compromise language on GIs in the TRIPS Agreement. Developing countries had little or no experience with GI protection, therefore their influence on the negotiation was minimal. The TRIPS Agreement language on GIs is a compromise (Section 3, Articles 22-24). It differentiates the level of

²¹ See Musungu, S. The Protection of Geographical Indications and the Doha Round: Strategic and Policy Considerations for Africa, QUNO IP Issue Paper 8, Geneva, 2008.





protection granted to wines and spirits from that accorded to other products. It does not specify what legal system must be used to protect GIs, but requires that legal means are available for interested parties to prevent a) the use of any means in the designation or presentation of a good that indicates or suggests that the good in question originates in a geographical area other than the true place of origin in a manner which misleads the public as to the geographical origin of the good; and (b) any use which constitutes an act of unfair competition. The TRIPS Agreement includes clauses allowing the continued use of a foreign GI when the term has become generic in the national context. The TRIPS Agreement provides that only GIs that are protected nationally, can gain protection in a third country, under Article 29.

-The multilateral register for wines and spirits

46. During the Uruguay Round there was discussion on a system of notification and registration of GIs for wines (later extended also to cover spirits), but no agreement. Thus, Article 23.4 calls for the negotiation of the register is to facilitate the protection of GIs. This negotiation is the only one to take place in a dedicated "special session" of the TRIPS Council. To date no agreement has been reached, though the special sessions continue to be held.

47. The positions among developing countries, just as among developed countries, on TRIPS issues in relation to GIs – the register for wines and spirits, and the possible extension of higher protection afforded to wines and spirits to all products, are very divided. This contrasts with the solid coalition of developing countries on the TRIPS-CBD issue.

The extension of GI protection

48. Another issue under discussion is the extension of the level of protection provided for wines and spirits to all products. This would mean that right holders would have no need to demonstrate that the use of a designation of a good that indicates or suggests that the good in question originates in a geographical area other than the true place of origin, misleads the public as to the geographical origin of the good or constitutes an act of unfair competition.

49. There has been little change in the negotiation positions, and thus no outcomes, on the GI issues in relation to TRIPS. A recent development that may lead the European Union and other "friends of GIs" to pursue less the agenda in the WTO is the recent adoption of the Geneva Act to the Lisbon Treaty on the Protection of Appellations of Origin in the context of WIPO²². Moreover, the European Union has been able to effectively negotiate bilaterally to pursue via trade agreements (including Economic Partnership –EPA– agreements with African countries) to increase protection for European GIs in the partner country. The GIs to receive protection in the other

²² See <u>http://www.wipo.int/treaties/en/registration/lisbon/</u>.





jurisdiction are usually negotiated on the basis of a list. The list tends to favour the European Union that has a large number of GIs, as opposed to the partner country with very few GIs protected domestically and that it may seek to protect in the European Union.

Status of the GI Issues and the CBD - TRIPS Issue

50. The WTO Director General issued a status report on the negotiations on the issues of the register for wines and spirits, the extension of GIs, and the relationship of TRIPS-CBD (TN/C/W/61 – also circulated as WT/GC/W/633). Since then, no significant changes in negotiation positions, or specific outcomes, have been achieved.

51. The Special Session of the TRIPS Council is currently tasked with negotiating a multilateral system for notifying and registering wines and spirits that are given higher protection in TRIPS than other geographical indications, established under Article 23.4. However, given the stalled negotiations on TRIPS "implementation issues" – on the relationship between the CBD and TRIPS (disclosure requirement proposed as new Article 29*bis*) and the extension of higher level of protection for geographical indications beyond wines and spirits under Article 23 –, some members propose to include discussion on TRIPS "implementation issues" in the TRIPS Special Session. Others oppose.

IV. THE EXTENSION OF TRANSITION PERIODS FOR LDCs

African Position

52. The African Group position on TRIPS related issues has been to support the LDCs in retaining the key flexibility that they have of not implementing the provisions of the TRIPS Agreement, under Article 66.1.

Recommendation

53. The African Group should support future extension of the transition periods for LDCs. No decision is necessary on this matter by the General Council until 2021.

54. In ensuring coherence between the LDC and African Group position at the multilateral level with regional level positions, African countries should work to ensure that LDCs are also be exempted from TRIPS compliant or TRIPS plus obligations in regional intellectual property frameworks, i.e. ARIPO and OAPI and initiatives under discussion, i.e. the Pan African Intellectual Property Organization (PAIPO).

55. Effective utilization of the TRIPS flexibilities – including not making patent protection available – is critical for the industrial development of African countries.





Priority must be placed in creating the space for local African firms to access, emulate and adapt existing technologies and develop their productive capacities through technological learning. African regional economic communities (REC) such as the East African Community have adopted regional level policies encouraging the use of TRIPS flexibilities to facilitate regional manufacturing and trade in medicines.²³ Bangladesh to date is the only LDC that has managed to build capacity in the pharmaceutical sector, making effective use of TRIPS flexibility of the transition period available not to comply with TRIPS obligations.

56. This effective use of the transition period to build technological capacity now allows the local industry in Bangladesh to meet over 70 per cent of domestic demand for essential medicines and be able to export generics to third countries.²⁴ There is ample scope for other African RECs or the future Continental Free Trade Area (CFTA) to provide for measures utilizing the TRIPS flexibilities for facilitating the development of local industries, and build regional capacity and pool resources.

Current State of Play

57. The special situation and needs of Least Developed Countries in Africa is recognised in the TRIPS Agreement. Article 66.1 of the TRIPS Agreement accorded a 10-year transition period to LDCs, In recognition of their special needs and requirements. Article 66.1. states that "In view of the special needs and requirements of least-developed country Members, their economic, financial and administrative constraints, and their need for flexibility to create a viable technological base...". This article recognizes that the creation of a "viable technological base" cannot be made in the context of a high level of intellectual property protection, as required by the TRIPS Agreement. Learning through access to foreign technologies and imitation are essential at early stages of development.

58. The transition period expired on 1 January 2006. A special decision²⁵ was made in June 2002, by the TRIPS Council in relation to pharmaceutical products, pursuant to the instruction given to the Council by the 2001 Doha Ministerial Declaration on TRIPS and Public Health. It exempted LDCs from applying sections 5 (patents) and 7 (test data) of Part II of TRIPS and from enforcing rights under those provisions until 1 January 2016. In addition, a decision of the General Council of July 2002,²⁶ exempted LDCs until 2016

²³ See Nirmalya Syam (2014), Transition Period for TRIPS Implementation for LDCs: Implications for Local Production of Medicines in the East African Community, Research Papers 59, South Centre, available at https://www.southcentre.int/wp-content/uploads/2014/12/RP59_Transition-Period-for-TRIPS-

<u>Implementation-for-LDCs_EN.pdf</u>; see also Nirmalya Syam (2014), Regional Pooled Procurement of Medicines in the East African Community, Research Papers 53, South Centre, <u>https://www.southcentre.int/wp-content/uploads/2014/09/RP53_Regional-Pooled-Procurement-of-Medicines-in-EAC_ENRev.pdf</u>.

²⁴ Mohammad Aktarul Alam Chowdhury (2014), "TRIPS and Innovative Capacity of Bangladesh's Pharmaceutical Industry: Promotion of Access to Essential Medicine", *IIUC Studies*, vol.10 & 11, 111-26.
²⁵ IP/C/25.

 $^{^{26}}$ WT/L/478.



SOUTH



Original: English

from obligations under Article 70.9 (exclusive marketing rights for pharmaceutical products) of the TRIPS Agreement. The justification of the extension specifically applicable to pharmaceuticals is of particular importance to facilitate access to medicines at low cost. The majority of LDCs' population would be otherwise unable to receive needed medical treatments. In addition, upon a collective request by the LDCs, the general transition period accorded by article 66.1 was extended until July 2013 (for 7 years and a half) by a decision of the Council for TRIPS.²⁷ This decision included a "norollback" clause, which essentially prevented LDCs from providing a reduced level of intellectual property protection if their laws contained provisions compliant with or closer to the TRIPS standards. Before the expiration of the extended transitional period in July 2013, and in exercising the right recognized in article 66.1,28 LDCs requested a new extension not subject to an arbitrary term, but that would end when a country benefiting from the extension ceases to be an LDC in accordance with the applicable indicators. However, developed countries refused to grant the extension on the requested terms; they only reluctantly agreed to extend the transitional period until July 2021.

59. LDCs are currently exempted from implementing the TRIPS Agreement until 2021. As a result of arduous negotiations, LDCs are separately exempted from obligations with respect to pharmaceutical products and the obligations under Article 70.8 and Article 70.9 under the TRIPS Agreement for a longer period, until 2033, at the request of the LDCs (WTO document IP/C/W/605). LDCs are eligible for further extension of these periods. The basis for these extensions is in-built in the TRIPS Agreement in Article 66.1, in recognition that LDCs lack and need to create a sound and viable technological base.

60. The African group position on TRIPS related issues should support the LDCs in retaining this key flexibility by supporting future extension of the transition periods for LDCs.

²⁷ IP/C/40.

²⁸ "The Council of TRIPS *shall*, upon duly motivated request ... *accord* extensions of this period" (article 66.1; emphasis added).





V. NON-VIOLATION AND SITUATION COMPLAINTS FOR DISPUTE SETTLEMENT UNDER THE TRIPS AGREEMENT

African Position

61. The African group has expressed support for the recurring extension of the moratorium on the application of non-violation and situation complaints to the TRIPS Agreement. The African Group has not made any written submission on this issue.

62. Specifically with regard to TRIPS, non-violation complaints could enable legal challenges to regulatory and public policy measures that may be consistent with the obligations under the TRIPS Agreement, such as compulsory licenses or parallel importation of medicines for African countries with insufficient manufacturing capacities. Thus, it could effectively narrow the scope of TRIPS flexibilities for African countries. Non-violation complaints would seriously impair the balance of rights and obligations enshrined under TRIPS. In particular, it can significantly limit the ability of the African countries to use the TRIPS flexibilities to advance public health objectives. If non-violation and situation complaints were to apply to disputes under TRIPS, measures implemented in furtherance of policies such as the EAC regional policy on the use of TRIPS flexibilities can be challenged in a WTO dispute. If other African RECs or the future Continental Free Trade Area (CFTA) calls for measures utilizing the TRIPS flexibilities for facilitating the development of local industries, non-violation and situation complaints development of local industries, non-violation and situation complaints were to apply the sum of the trained to the trained of the African RECs or the future Continental Free Trade Area (CFTA) calls for measures utilizing the TRIPS flexibilities for facilitating the development of local industries, non-violation and situation complaints could be a serious impediment.

Recommendation

63. African countries should join the coalition of developing countries – including Egypt and Kenya – that have proposed a decision to set a permanent ban on the application of these complaints with respect to the TRIPS Agreement (WTO document IP/C/W/385/Rev 1). The reverse would be detrimental to African countries. The applicability of such complaints would deter many countries from making effective use of the flexibilities available under the TRIPS Agreement and seriously impair the balance of rights and obligations. Moreover, there are limited resources and legal capacity to handle such cases.

64. African countries should also interpret Article 64.2 to mean that in case the moratorium on the application of non-violation and situation complaints is not extended in 2017, the complaints would not automatically apply to the TRIPS Agreement. Under a strict reading of Article 64.2, these disputes cannot apply until the time members agree to the scope and modalities of their application in respect to the TRIPS Agreement.

Current State of Play

65. Currently, if African countries or the future CFTA implement measures to fully utilize the TRIPS flexibilities in relevant sectors, such measures cannot be challenged by





initiating a complaint under the WTO dispute settlement mechanism, as they do not violate the provisions of the TRIPS Agreement. However, under other WTO Agreements such as the General Agreement on Tariffs and Trade (GATT) and the General Agreement on Trade in Services (GATS), a measure may be challenged under a WTO dispute even if the said measure is in compliance with the obligations under the relevant agreement. Such complaints are known as non-violation or situation complaints. At present there is a moratorium on the application of such complaints to disputes under the TRIPS Agreement. If non-violation and situation complaints are allowed under TRIPS, it can render measures taken by African countries to utilize the TRIPS flexibilities the subject of a non-violation or situation complaint in a WTO dispute.

66. Non-violation or situation complaints are foreseen where the attainment of the objectives of the Agreement is impeded or the benefits accruing under that Agreement are nullified or impaired due to such measures or the existence of any other situation. Non-violation complaints seek to render international liability for injurious consequences arising out of lawful acts. While traditionally such complaints were applicable in exceptional circumstances to disputes arising under the GATT, after the Uruguay Round²⁹ of negotiations leading to the establishment of the WTO, the admissibility of such complaints was extended to disputes arising under the General Agreement on Trade in Services (GATS).

67. There was no agreement on whether to allow such complaints under the TRIPS Agreement. As the negotiations on this issue remained inconclusive at the end of the Uruguay Round, a 5 year moratorium on non-violation complaints was provided under Article 64.2 of TRIPS. However, the TRIPS Council has been unable to arrive at an agreement on this issue. The moratorium has been extended 6 times by the WTO Ministerial Conference, with the latest extension made by the tenth Ministerial Conference in Nairobi till the eleventh Ministerial Conference to be held in 2017.³⁰

68. The dispute settlement system is an integral part of the WTO, with rules and procedures pertaining to the settlement of disputes, commonly known as the dispute settlement understanding (DSU). The DSU applies to dispute brought under TRIPS.³¹ Article 64.1 of the TRIPS Agreement made the dispute settlement provisions of GATT

²⁹ The Uruguay Round refers to the eighth round of multilateral trade negotiations (MTN) under the framework of the GATT that was launched in 1986 at Punta del Este in Uruguay and was concluded in 1994 leading to the establishment of the WTO. See *Understanding the WTO: Basics – The Uruguay Round* available at <u>https://www.wto.org/english/thewto_e/whatis_e/tif_e/fact5_e.htm.</u>

³⁰ See WTO (2015), TRIPS Non-Violation and Situation Complaints, Ministerial Decision of 19 December 2015, (WT/MIN(15)/41) (WT/L/976), available at https://www.wto.org/english/thewto_e/minist_e/mc10_e/nairobipackage_e.pdf.

³¹ The WTO inherited its dispute settlement system with some modifications from the dispute settlement mechanism under the 1979 Understanding on Dispute Settlement under GATT 1947 (amended in 1989) which pre-existed the establishment of the WTO. The WTO DSU introduced speedier procedures with strict time limits, establishing a right to a panel, automatic adoption of panel reports in the absence of negative consensus, and the potential for review by an Appellate Body.





(Articles XXII and XXIII) applicable to TRIPS. In terms of Article XXIII of GATT, a WTO member could initiate the dispute settlement process on the following grounds:

- a) the failure of another member to implement its obligations under the agreement concerned, or
- b) due to the application of a measure even if it is not in conflict with the agreement concerned,
- c) or due to any other situation.

69. The provisions under GATT Article XXIII (b) and (c) allowing for non-violation and situation complaints were introduced to ensure that negotiated tariff concessions under GATT are not undermined by measures that the GATT did not regulate such as competition policy, subsidies or product regulations serving proper domestic policy goals.

70. The GATT/WTO jurisprudence on non-violation and situation complaints have also varied from interpretations that restrict the scope of such complaints to those that expand the scope of such complaints.³² However, in other cases in GATT/WTO jurisprudence on non-violation complaints the scope of such complaints has been interpreted broadly.³³ For example, in the *EC-Asbestos* case the Appellate Body rejected the contention of the EC that public health measures under health exceptions in the GATT were excluded from the scope of non-violation complaints.³⁴

71. Since the introduction of non-violation complaints in GATT – over 60 years – only three members (US, EC and Canada) have brought non-violation complaints. One commentator has observed that non-violation complaints are mainly open to countries with significant legal human capital,³⁵ making it an unaffordable luxury to most WTO members. Moreover, it has been observed that the lack of uniformity and clarity regarding non-violation complaints in WTO jurisprudence has jeopardized the security and predictability of the WTO dispute settlement system.³⁶ While in some cases the

http://www.iatp.org/files/Remedies_in_the_WTO_Dispute_Settlement_System_.htm.

³² Ibid., 316-18.

³³ Most notably in the *EEC-Citrus* case the panel adopted a broader interpretation of the scope of nonviolation complaints to the US could have reasonably expected under the most favoured nation (MFN) obligations under Article 1 of GATT, though the preferential tariffs were in existence at the time of negotiation of the tariff concessions between the US and EEC.GATT Panel Report, *European Community – Tariff Treatment on Imports of Citrus Products from Certain Countries in the Mediterranean Region*, Report of the Panel, L/5776, 7 February 1985, unadopted, https://www.wto.org/gatt_docs/English/SULPDF/90080242.pdf.

³⁴ WTO, *European Communities – Measures Affecting Asbestos and Asbestos-Containing Products*, Report of the Appellate Body, WT/DS135/AB/R, 12 March 2001, adopted, paragraphs 182-91, <u>https://docs.wto.org/dol2fe/Pages/FE_Search/DDFDocuments/1236/Q/WT/DS/135ABR.pdf</u>.

³⁵ Henrik Horn and Petros C. Mavroidis (1999), Remedies in the WTO Dispute Settlement System and Developing Interests,

³⁶ Matthew Stilwell and Elisabeth Tuerk (2001), Non-Violation Complaints and the TRIPS Agreement: Some Considerations for WTO Members, Centre for International Environmental Law, <u>http://www.ciel.org/wp-content/uploads/2015/03/Nonviolation_Paper1.pdf</u>.





panels have refrained from interpreting what constitutes non-violation complaints, in other cases panels have adopted diverse and conflicting interpretations. Nor have the panels been able to consistently define the scope of application of non-violation complaints.

72. Almost two decades of discussions on the scope and modalities regarding nonviolation complaints under TRIPS have remained inconclusive. Both developed and developing countries raised similar concerns in their submissions to the TRIPS Council. In 1999, a submission by Canada (IP/C/W/127) stated that applying non-violation complaints to IP may constrain members' ability to introduce important measures in many vital areas.³⁷ Echoing the concerns raised by Canada, in 2002 a group of developing countries (Argentina, Bolivia, Brazil, Colombia, Cuba, Ecuador, Egypt, India, Kenya, Malaysia, Pakistan, Peru, Sri Lanka and Venezuela) made a submission³⁸ in the TRIPS Council stating that the application of non-violation and situation complaints in TRIPS is unnecessary and proposed that the TRIPS Council should recommend to the Ministerial Conference that non-violation and situation complaints be determined to be inapplicable to TRIPS. After the 2013 Bali Ministerial Conference, the US submitted a paper at the WTO TRIPS Council session in June 2014 stating that in the absence of a consensus to extend the moratorium, the drafters of TRIPS envisioned that non-violation and situation complaints would apply to TRIPS. ³⁹ It also relied on the decisions in the EC-Asbestos and Korea-Government Procurement cases to argue that non-violation complaints are not restricted to tariff concessions only. Further, the US stated that nonviolation complaints under TRIPS will not have a negative impact on the use of TRIPS flexibilities as the use of TRIPS flexibilities was foreseen at the time of negotiation of the TRIPS Agreement. In response to the US submission, a group of developing countries along with Russia made a joint submission to the TRIPS Council session in June 2015 reaffirming their position that non-violation and situation complaints are unnecessary and therefore the TRIPS Council should recommend that such complaints shall not apply to TRIPS.⁴⁰ The Chair of the TRIPS Council has been engaged in informal consultations on this issue but positions of member States remain unchanged.

https://docs.wto.org/dol2fe/Pages/FE_Search/DDFDocuments/125103/q/IP/C/W599.pdf

³⁷ WTO, Non-Violation Nullification or Impairment Under the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS), Communication from Canada, IP/C/W/127, 10 February 1999, <u>https://docs.wto.org/dol2fe/Pages/FE_Search/DDFDocuments/26151/Q/IP/C/w127.pdf</u>.

³⁸ WTO, Non-Violation Nullification or Impairment Under the TRIPS Agreement, Communication from Argentina, Bolivia, Brazil, Colombia, Cuba, Ecuador, Egypt, India, Kenya, Malaysia, Pakistan, Peru, Sri Lanka and Venezuela, IP/C/W/385, 30 October 2002, https://docs.wto.org/dol2fe/Pages/FE_Search/DDFDocuments/29081/Q/IP/C/W385.pdf

³⁹ WTO, Non-Violation Complaints Under the TRIPS Agreement, Communication from the United States, IP/C/W/599, 10 June 2014,

⁴⁰ WTO, Non-Violation and Situation Nullification or Impairment Under the TRIPS Agreement, Communication from Argentina, Bolivia, Brazil, China, Colombia, Cuba, Ecuador, Egypt, India, Indonesia, Kenya, Malaysia, Pakistan, Peru, Russia, Sri Lanka and Venezuela, IP/C/W/385/Rev.1, 22 May 2015, <u>https://docs.wto.org/dol2fe/Pages/FE_Search/FE_S_S009-</u>

DP.aspx?language=E&CatalogueIdList=135651,134755,132276&CurrentCatalogueIdIndex=2&FullTextHash=.



SOUTH



Original: English

73. At the end of the Uruguay Round of negotiations, no official history of the negotiations was presented to the negotiators for their approval.⁴¹ In the absence of any approved history of the negotiations, attempts to interpret the intent of the drafters of TRIPS from various alternative draft texts considered during the negotiations will not be a prudent approach to take.⁴² Notably, in the *India – Quantitative Restrictions* case, the panel had turned down a negotiating history sought to be deduced by India on the basis of various draft texts and comparing it with the language of the final agreed text.⁴³ Therefore, the intent of the drafters of TRIPS should only be gathered from the literal reading of Article 64. Article 64 clearly states that non-violation and situation complaints shall not apply to TRIPS during an initial moratorium of five years that can be extended by consensus. It also states that any decision regarding the scope and modalities for applying non-violation and situation complaints must also be adopted by consensus.

74. It would be untenable to assume that the negotiators of TRIPS intended a situation to arise where non-violation and situation complaints would be applicable under TRIPS due to non-extension of the moratorium but there is no agreement on the scope and modalities for the same. The purpose of the moratorium is to provide space for negotiations without prejudging the outcome. While so far members have recommended extension of the moratorium for continued discussions on this issue, it is possible for members to recommend either that non-violation and situation complaints would apply to TRIPS with defined scope and modalities, or members could recommend that non-violation and situation complaints shall not apply to disputes arising under TRIPS. It should be noted that a general principle of international law is that the provisions of the treaty must be implemented by the parties in good faith.⁴⁴ Thus, WTO panels are empowered to correct any instance of implementation of the provisions of TRIPS in bad faith.

⁴¹ See Amelia Porges (2015), "The Legal Affairs Division and law in the GATT and the Uruguay Round", in Gabrielle Marceau (ed.), A HISTORY OF LAW AND LAWYERS IN THE GATT/WTO: THE DEVELOPMENT OF THE RULE OF LAW IN THE MULTILATERAL TRADING SYSTEM (Cambridge University Press, Cambridge, UK), p.231. No official record of the negotiations was produced for most important issues and some key decisions took place outside the multilateral context. For example, the Chairman of the Institutions Group, Lacarte Muro, repeatedly admonished the negotiators that there would be no official negotiating history for the Group's work, and they would have to accomplish their goals in the text itself.

⁴² In fact the issue of dispute settlement in TRIPS received the attention of negotiators only in 1993 when the GATT Director-General Peter Sutherland renewed intensive talks to conclude the Uruguay Round. It was only at this stage that the issue of the inapplicability of the original GATT provision on non-violation and situation complaints came to the fore, with India and other countries raising this issue. As disagreement on this question threatened to block consensus on the entire bundle of the Uruguay Round texts, a compromise was agreed to under Articles 64.2 and 64.3. See Kanaga Raja (2015), "US, Big Pharma pushing TRIPS", 16 NV dispute moratorium SUNS #8042, end on Iune 2015, to http://www.twn.my/title2/wto.info/2015/ti150615.htm.

⁴³ See WTO, India – Quantitative Restrictions on Imports of Agricultural, Textile and Industrial Products, WT/DS90/R, 6 April 1999, paragraph 5.111, <u>https://docs.wto.org/dol2fe/Pages/FE_Search/DDFDocuments/22369/Q/WT/DS/90R.pdf.</u>

⁴⁴ See Vienna Convention on the Law of Treaties, Article 31.1.





ANNEX 1

African Group, Taking Forward the Review of Article 27.3(b) of the TRIPS Agreement, WTO document IP/C/W/404, 26 June 2003

PROPOSED DECISION ON TRADITIONAL KNOWLEDGE

1. This Decision, adopted as a result of the review of Article 27.3(b), shall be an integral part of the TRIPS Agreement.

2. Rights given effect and to be protected by all Members

(a) Traditional knowledge is a category of intellectual property rights hereby recognised and protected in accordance with this Decision. Members shall protect and enforce rights in respect of traditional knowledge in accordance with the provisions of this Decision. Members may adopt *sui generis* systems for more extensive protection.

(b) In co-operation with all relevant international and civil society organizations particularly associations of local communities and traditional practitioners, the WTO shall prepare and adopt programmes for the development and review, as may be necessary from time to time, of the protection of traditional knowledge and enforcement of rights conferred under this Decision in respect of traditional knowledge.

(c) The rights relating to traditional knowledge that shall be protected include, in relation to any local community or traditional practitioners, the right for such community or practitioner to:

- (i) respect for their will and decisions on whether or not to commercialise their knowledge;
- (ii) respect and honour of any sanctity they attach to their knowledge,
- (iii) give prior and informed consent for any access and any intended use of their knowledge,
- (iii) full remuneration for their knowledge,
- (iv) prevent third parties from using, offering for sale, selling, exporting, and importing, their knowledge and any article or product in which their knowledge is input, unless all the requirements under this Decision have been met.





(d) The existence of traditional knowledge in any form or at any stage shall defeat the novelty and inventiveness requirements for purposes of patents and originality for purposes of copyrights under any laws of all Members.

(e) Where:

- (i) traditional knowledge has been a lead to the invention,
- (ii) any invention that qualifies for patentability has derived at any stage from traditional knowledge,
- (iii) any invention is based on in situ genetic resources of any Member,

then, no intellectual property rights shall be granted or protected in any Member unless the requirements on access to genetic resources under the Convention on Biological Diversity have been fully complied with.

(f) Members shall require in their laws that any intellectual property rights granted in breach of this Decision shall, without any further requirements as to procedure other than this provision, be cancelled forthwith. No intellectual property rights shall be granted or protected without due recognition of the traditional knowledge involved in accordance with this Decision. In accordance with this paragraph, Members shall provide for the ex-officio cancellation of any intellectual property rights that breach this Decision.

4. Documentation of Traditional Knowledge and Local Communities

(a) Members may document traditional knowledge in their territories and designate a competent authority to continually carry out this exercise. Members may also maintain registers of local communities and traditional practitioners for administrative purposes, but non-registration shall not prejudice the rights of any local community or traditional practitioner under this Decision.

(b) Members may make appropriate arrangements for the establishment and maintenance of electronic and other registers on traditional knowledge that shall be public documents subject to reasonable regulations they may put in place, and for applications from any local communities or traditional practitioners to the competent authority to register their traditional knowledge.

(c) Local communities and the competent authorities shall have an exclusive right in perpetuity to any information that is documented or entered in the register, to prevent any access or use they have not expressly authorised or any application that is inconsistent with the rights of local communities and traditional practitioners under this Decision.





5. Institutional Arrangements

(a) The Committee on Traditional Knowledge and Genetic Resources is hereby established.

- (b) Its functions shall include:
 - (i) developing and reviewing this Decision and any other instruments,
 - (ii) overseeing and making recommendations on the protection of traditional knowledge and enforcement of the rights of the Members,
 - (iii) following activities and developments in relevant regional and international intergovernmental organizations,
 - (iv) providing forums for dialogue on traditional knowledge, and
 - (v) conducting studies and making recommendations to Members and relevant organizations on protection of traditional knowledge under the provisions and within the framework of other international and regional instruments.

(c) Every Member shall establish a competent authority and a central enquiry point to provide information and carry out designated functions arising from this Decision.

6. Meaning

(a) Traditional knowledge includes, but is not to be limited to, knowledge systems, innovations and adaptations, information, and practices of local communities or indigenous communities as understood within the territory of the Member, relating to any type of medicine or cures, agriculture, use and conservation of biological material and diversity, and any other aspect of economic, social, cultural, aesthetic or other value.

(b) Traditional knowledge is not static but continues to evolve, and its nature relates to the manner it develops rather than to its antiquity.

(c) For purposes of this Decision, traditional knowledge includes folklore unless the context requires otherwise or it is provided otherwise; and local communities includes indigenous peoples subject to definitions that Member may adopt within their domestic laws.