

MODULE X

TRIPS AND PUBLIC HEALTH

A Introduction

Public health has been one of the most extensively discussed aspects of the TRIPS Agreement, both in terms of the treaty text itself and its implementation at the domestic level. Its significance is borne out by a proclamation at the ministerial level, the 2001 Doha Declaration on the TRIPS Agreement and Public Health (Doha Declaration),¹⁰⁸ and by the ensuing amendment of the Agreement itself, the first amendment of any WTO multilateral trade agreement, undertaken specifically to provide the most vulnerable countries with an additional secure legal pathway to gain access to affordable generic medicines.

The TRIPS Agreement represents an attempt at the multilateral level to achieve the difficult task of balancing the interest of providing incentives for research and development of new drugs with the interest of making these drugs as widely accessible as possible to patients needing them. Consequently, in setting minimum standards for the protection and enforcement of IPRs, the TRIPS Agreement recognizes the right of members to take various kinds of measures to qualify or limit IPRs, including for public health purposes. The Doha Declaration expressly recognized the importance of creating a positive, mutually reinforcing link between the IP system and access to medicines. It responded to earlier concerns expressed about the possible implications of the TRIPS Agreement for public health, in particular access to patented medicines, and ultimately led to the amendment of TRIPS. It also clarified specific ‘flexibilities’ under TRIPS relating to public health.

If a member wants to avail itself of these flexibilities under the Agreement, it may need to implement them into its domestic law in order to be in a position to make use of them. That is, the mere recognition of these flexibilities as legal options under the international TRIPS Agreement does not necessarily mean that they are available under members’ national laws. Further, the TRIPS Agreement – and the IP system more generally – is only one element of the broader, more complex sets of measures that address the challenge of access to medicines, which also includes such important factors as the public health system in general, drug regulatory authorities, financing, health insurance, infrastructure, procurement regimes, competition law and enforcement, as well as import tariffs applied to pharmaceutical products.

The issues raised are complex and at times controversial, and the range of practical experience diverse. This Guide does not seek to address them in their entirety but simply lays out key aspects of the TRIPS Agreement that relate to the wider issues. This

¹⁰⁸ Declaration on the TRIPS Agreement and Public Health, [WT/MIN\(01\)/DEC/2](#) (‘Doha Declaration’), reproduced in Annex 6 to this Guide.

module provides an overview of work done in the WTO on IP and public health. It discusses the flexibilities within the TRIPS Agreement that are most relevant to public health. In particular, it looks into how the Doha Declaration and the special compulsory licensing system, also referred to as the ‘Paragraph 6 System’, were formalized in the amendment of the Agreement.

The text of the amended TRIPS Agreement, the Doha Declaration, the decision that established the special compulsory licensing system, and the decision adopting the Protocol Amending the TRIPS Agreement are reproduced in Annexes 1, 6, 7, and 8 to this Guide.

B Doha Declaration on the TRIPS Agreement and Public Health

1 Concerns that triggered the discussions

The TRIPS Agreement was negotiated to ensure that members could take various kinds of measures to qualify or limit IPRs, including for public health purposes. However, some uncertainty arose as to whether the flexibilities in the TRIPS Agreement and the interpretation given to them were sufficient to ensure that it is supportive of public health, especially in promoting affordable access to existing medicines while also promoting research and development of new ones:

- first, different views were expressed about the nature and scope of the flexibilities in the TRIPS Agreement, for example in regard to compulsory licensing and parallel imports;
- second, questions were raised as to whether these flexibilities would be interpreted by the WTO and its members in a broad, pro-public health way; and
- third, there was concern about the extent to which members would feel free to use to the full these flexibilities without the fear of coming under pressure from their trading partners.

With a view to effectively addressing these concerns, the Doha Declaration contains some general statements on the relationship between the TRIPS Agreement and the protection of public health, clarifies some of the flexibilities incorporated into the TRIPS Agreement, and also provides some instructions for further work.

2 Scope

Paragraph 1 of the Doha Declaration is generally considered as defining the scope of its application. In this paragraph, ministers recognized the gravity of the public health problems afflicting many developing countries and LDCs, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics. This language, which was heavily negotiated, makes it clear that the Doha Declaration is not limited to the diseases that are explicitly mentioned there, but is broader in its application.

3 General statements

The general statements provide important guidance to both individual members and, in the event of disputes, WTO dispute settlement bodies. As part of those statements, the Doha Declaration emphasizes that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health and reaffirms the right of members to fully use the flexibilities available in the TRIPS Agreement for this purpose. It thus signals an acceptance by all members that they will not seek to prevent other members from using TRIPS flexibilities.

In addition, the Doha Declaration makes it clear that the TRIPS Agreement should be interpreted and implemented in a manner supportive of members' right to protect public health and, in particular, to promote access to medicines for all. Indeed, the *Australia – Tobacco Plain Packaging* (DS435, 441, 458, 467) Panels noted that the Doha Declaration serves to underscore that the term 'unjustifiably' in Article 20 provides members 'a wide degree of latitude to implement measures to protect public health'.¹⁰⁹

Furthermore, the Doha Declaration highlights the importance of the objectives and principles of the TRIPS Agreement for the interpretation of its provisions. Although it does not refer specifically to Articles 7 and 8 of the TRIPS Agreement, it refers to 'objectives' and 'principles', words that correspond to the title of each article and were understood by the *Australia – Tobacco Plain Packaging* Panels to refer to them. The same Panels also expressed the view that paragraph 5 of the Doha Declaration may be considered to constitute a subsequent agreement among members to interpret each provision of the TRIPS Agreement in light of these provisions.¹¹⁰ On appeal, the Appellate Body declined to address the legal status of the Declaration but agreed with the Panels that paragraph 5 reflects 'the applicable rules of interpretation, which require a treaty interpreter to take account of the context and object and purpose of the treaty being interpreted'. See Module I, section B1 for additional discussion of Articles 7 and 8.

Finally, as another expression of the continual search for the right balance between incentivizing R&D into new medicines and providing access to them, the Doha Declaration recognizes the importance of IP protection for the development of new medicines, while also noting the concerns about the effects of IP protection on prices.

4 Clarification of flexibilities

The Doha Declaration contains a number of important clarifications of certain TRIPS flexibilities, while reiterating the commitment of members to the TRIPS Agreement.

¹⁰⁹ Panel Reports, *Australia – Tobacco Plain Packaging*, para. 7.2348.

¹¹⁰ Panel Reports, *Australia – Tobacco Plain Packaging*, para. 7.2409.

With respect to compulsory licences and emergency situations, it clarifies that each member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted. This, for example, is a useful corrective to the views that have sometimes been heard implying that some form of emergency is a pre-condition for compulsory licensing. The TRIPS Agreement does indeed refer to national emergencies or other circumstances of extreme urgency in connection with compulsory licensing (Article 31(b)). However, this reference is only to indicate that, in these circumstances, the usual condition that efforts must be first made to seek a voluntary licence does not apply. In any event, the Doha Declaration confirms that each member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency and that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent such circumstances.

BOX X.1 TRIPS FLEXIBILITIES AS CLARIFIED BY THE DOHA DECLARATION

While the concept of TRIPS flexibilities is broader, the Doha Declaration explicitly recognizes certain specific measures:

- The right to grant compulsory licences and the freedom to determine the grounds.
- The right to determine what constitutes a national emergency or other circumstances of extreme urgency (with the understanding that this concept can include public health crises, such as those relating to HIV/AIDS, tuberculosis, malaria and other epidemics).
- The freedom for each member to establish its own regime for exhaustion without challenge, subject to the principle of non-discrimination.

In regard to the exhaustion of IPRs, which impinges on the possibility to parallel import originator medicines from third country sources, Article 6 of the TRIPS Agreement states that a member's practices in this area cannot be challenged under the WTO dispute settlement system. The Doha Declaration clarifies that the effect of this and other relevant provisions in the TRIPS Agreement is to leave each member free to establish its own regime without challenge – subject to the general TRIPS provisions prohibiting discrimination on the basis of the nationality of right holders. Accordingly, members can choose between national or international exhaustion and can also provide for different exhaustion regimes that apply to specific categories of IP rights or industry sectors. Under national exhaustion, a right holder can prevent importation of IP-protected products from other countries even if they have been put on the market there by the right holder or with the right holder's consent. Under international exhaustion, the right holder would not be able to do this since all IPRs would be held to have been exhausted by his earlier sale of the product. See also the discussion on exhaustion in Module I, section B5 and Box X.1.

5 *Transfer of technology*

The Doha Declaration also reaffirmed the commitment of developed countries regarding the provision of incentives to their enterprises and institutions to promote and encourage technology transfer to LDCs under Article 66.2. See Module I, section D3.

6 *Follow-up*

There were two specific instructions given by ministers in the Doha Declaration with respect to further work to be undertaken in the TRIPS Council, which were implemented as follows:

- Based on the Doha Declaration, a TRIPS Council Decision¹¹¹ extended the transition period for LDC members of the WTO until 1 January 2016 in regard to the protection and enforcement of patents and rights in undisclosed information with respect to pharmaceutical products. To complete this measure, a decision by the General Council¹¹² waived the otherwise applicable provision on exclusive marketing rights in Article 70.9 for the same period. Subsequent decisions of the TRIPS Council¹¹³ and General Council¹¹⁴ further extended the transition period and waived the provisions in Article 70.8 and 70.9 on ‘mailbox’ applications and exclusive marketing rights until 1 January 2033, or until such a date on which they cease to be an LDC member, whichever is earlier. These specific extensions of the transition period applying to pharmaceutical products are in addition to the general extension of the transition period given to LDCs for the implementation of the TRIPS Agreement until July 2034.¹¹⁵
- Following the instruction given by the Doha Declaration to seek an expeditious solution to the potential problems of countries with limited or no manufacturing capacities in making effective use of compulsory licensing, members agreed to establish a system of special compulsory licensing expressly for the export of pharmaceuticals to countries in need (sometimes termed the ‘Paragraph 6 System’ from its origins in this part of the Doha Declaration).

C **Special compulsory licencing system for pharmaceutical exports**

1 *The issue*

Paragraph 6 of the Doha Declaration recognized the problem of members with insufficient or no manufacturing capacities in the pharmaceutical sector in making effective use of compulsory licensing, and instructed the TRIPS Council to find an

¹¹¹ [IP/C/25](#).

¹¹² [WT/L/478](#).

¹¹³ [IP/C/73](#), reproduced in Annex 10 to this Guide.

¹¹⁴ [WT/L/971](#).

¹¹⁵ [IP/C/40](#), [IP/C/64](#) and [IP/C/88](#). [IP/C/88](#) is reproduced in Annex 9 to this Guide.

expeditious solution. Such countries would have to import under a compulsory licence if the needed medicine is patent-protected. This, in itself, is possible under the TRIPS Agreement as members can issue compulsory licences for importation as well as for domestic production. However, the potential problem identified was whether supply of generic medicines from patent-protected sources would be adequate. In other words, whether generic producers in countries with manufacturing capacity would be able to export sufficient quantities if the needed medicine was patent-protected in those countries. This is because the TRIPS Agreement limits the amount such countries can export under a compulsory licence; Article 31(f) requires that the production under a compulsory licence be ‘predominantly for the supply of the domestic market’. This constraint was expected to become more important in 2005 as some developing countries with significant generic industries and export capacity became obligated to provide patent protection for pharmaceutical products pursuant to the special transition arrangements in Article 65.4.

2 The solution: the special compulsory licensing system

Subsequent work in the TRIPS Council prepared the ground for the adoption of two important General Council decisions establishing the special compulsory licensing system. Each were adopted in the light of a Chairman’s statement setting out several key shared understandings of members on how the system would be interpreted and implemented.¹¹⁶

The General Council Decision of 30 August 2003 on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health¹¹⁷ (2003 Decision) waived under certain circumstances (i) the obligation on exporting members to ensure that compulsory licences are only granted for the purpose of predominantly supplying the domestic market (Article 31(f)) and (ii) the obligation on importing members to pay adequate remuneration to the right holder if a compulsory licence is granted (Article 31(h)).

Given the temporary nature of the waivers contained in the 2003 Decision, paragraph 11 of that Decision called for the TRIPS Council to prepare a permanent amendment to the TRIPS Agreement based, where appropriate, on the 2003 Decision. Agreement on such an amendment, through the insertion of a new Article 31*bis* and Annex to the TRIPS Agreement, was reached on 6 December 2005 when the General Council adopted a Protocol Amending the TRIPS Agreement¹¹⁸ (2005 Protocol) in the light of a Chairman’s statement reiterating the statement made in August 2003.

The 2005 Protocol closely tracks the text of the 2003 Decision. No substantive changes were made to the original system established by the 2003 Decision. It was

¹¹⁶ [WT/GC/M/82](#) and Corr.1, paras. 29-31; [WT/GC/M/100](#) and Corr.1, paras. 29-32.

¹¹⁷ [WT/L/540](#) and Corr.1, reproduced in Annex 7 to this Guide.

¹¹⁸ [WT/L/641](#), reproduced in Annex 8 to this Guide.

submitted to members for acceptance and entered into force on 23 January 2017, following acceptance by two thirds of the membership.¹¹⁹

This was the first amendment of any of the multilateral trade agreements since the WTO Agreement came into force in 1995. Article 31*bis* and the Annex, which became a permanent part of the TRIPS Agreement upon the entry into force of the 2005 Protocol in 2017, apply to those members who have notified their acceptance. Members that have yet to accept the 2005 Protocol continue to operate under the 2003 Decision. Given that the content of both legal regimes is identical, members benefit from the same flexibilities to enhance access to medicines regardless of whether a member has accepted the Protocol or not. References in this Guide to Article 31*bis* and/or the Annex to the TRIPS Agreement implicitly also refer to the corresponding paragraphs of the 2003 Decision; references to the ‘special compulsory licensing system’ consequently denote the mechanism established under both legal regimes.

BOX X.2 LEGAL BASIS FOR THE SPECIAL COMPULSORY LICENSING SYSTEM		
	Members who have accepted the 2005 Protocol	Members yet to accept the 2005 Protocol
Legal Basis	TRIPS Agreement, as amended on 23 January 2017	General Council Decision of 30 August 2003
Nature	Permanent part of TRIPS	Temporary waiver
Relevant Provisions	Article 31 <i>bis</i>	Paras. 2, 3, 6(i), 9, 10
	Annex	Paras.1, 2, 4, 5, 6(ii), 7, 8
	Appendix	Annex

3 Description of the system

The special compulsory licensing system established under the 2003 Decision and incorporated into the TRIPS Agreement through Article 31*bis* and the Annex to the Agreement provides for three distinct derogations from the obligations set out in Article 31 with respect to pharmaceutical products, subject to certain conditions. These derogations are meant to address a public health problem in the importing

¹¹⁹ [WT/Let/1236](http://www.wto.org/tripsamendaccept). A list of members which have notified their acceptance to the WTO is available at: www.wto.org/tripsamendaccept.

country, and a legal problem in the exporting country. Two of those modifications relate to Article 31(f), whereas the third refers to Article 31(h):

- First, the obligation of the exporting member under Article 31(f) to issue compulsory licences predominantly for the domestic market does not apply to the extent necessary to enable that member to authorize production and export of the needed pharmaceutical products under a compulsory licence to those countries that do not have sufficient capacity to manufacture them. This derogation is subject to certain conditions to ensure transparency in the operation of the system and to ensure that only countries with insufficient domestic capacity import under it. It also provides for safeguards against the diversion of products to markets for which they are not intended (Article 31bis.1 and Annex to the TRIPS Agreement, para. 2).¹²⁰
- Second, the requirement under Article 31(h) to pay adequate remuneration for compulsory licences is modified to avoid double remuneration of the right holder. If a compulsory licence has to be granted in both the exporting and the importing countries, remuneration need only be paid in the exporting country (Article 31bis.2).
- Third, a further derogation to Article 31(f) enables a WTO member to export products manufactured or imported under a compulsory licence more easily amongst members of a regional trade agreement (RTA) at least half the membership of which consists of LDCs (Article 31bis.3).

BOX X.3 THE SPECIAL COMPULSORY LICENSING SYSTEM IN A NUTSHELL

The scenario

The system is not intended to be a panacea for procuring medicines, but addresses a particular problem that was identified in the Doha Declaration. The system provides a specific legal avenue for an eligible member to procure medicines in the following circumstances:

- a member wants to import a pharmaceutical product, which it cannot produce locally, from a generic producer in another member (exporting member);
- the product is covered by a patent/patents in the exporting member; and
- there is a need in the exporting member for a compulsory licence to enable the generic production of the needed pharmaceutical product exclusively for export, including where the supply of the non-predominant part of the production under an existing compulsory licence to service the exporting member's domestic market cannot meet the needs of the importing member.

¹²⁰ Although parenthetical references are made here and in the following paragraphs to the relevant provisions of the amended TRIPS Agreement, WTO members that are yet to accept the 2005 Protocol operate under the corresponding provisions of the 2003 Decision.

BOX X.3 THE SPECIAL COMPULSORY LICENSING SYSTEM IN A NUTSHELL

The requirements

The essential steps that need to be taken to exercise this flexibility are:

- the importing member informs the TRIPS Council of its intention to use the system (other than an LDC). This is a one-time notification. It also informs about the name of the product and the quantities it wants to import for each use;
- where the needed pharmaceutical product is patented in the importing member, that member confirms that it has granted or intends to grant a compulsory licence or, in the case of an LDC, states alternatively that it is availing itself of the additional transition period;
- the exporting member issues a compulsory licence that permits production and exportation and notifies the TRIPS Council of the grant of the compulsory licence and the conditions attached to it;
- the product is identified as having been produced under this system, such as through labelling or marking; and prior to shipment,
- details of the shipment(s) are posted on a website by the licensee, the address of which is notified to the TRIPS Council by the exporting member.

The special compulsory licensing system only deals with the freedom of third parties not having the right holder's permission to produce and fully export the desired pharmaceutical product patented – it does not deal with questions such as procurement policies or regulatory questions, which are dealt with by national systems in whatever manner members choose. For instance, the importing member may require regulatory approval before the product is imported for distribution to the public in its territory, especially if it is a new formulation that hasn't been distributed there before.

The system also recognizes the need to harness economies of scale for the purposes of enhancing purchasing power for, and facilitating the local production of, pharmaceutical products, as well as the desirability of promoting the transfer of technology and capacity building in the pharmaceutical sector in order to overcome the problem identified in paragraph 6 of the Doha Declaration.

(a) Scope and coverage

The special compulsory licensing system covers any patented products, or products manufactured through a patented process, of the pharmaceutical sector needed to address the public health problems as recognized in paragraph 1 of the Doha Declaration, including active ingredients necessary for their manufacture and diagnostic kits needed for their use (Annex to the TRIPS Agreement, para. 1(a)).

(b) Eligible importing members

The following members qualify as eligible importing countries (Annex to the TRIPS Agreement, para. 1(b)):

- LDCs, which are automatically eligible to import under the system;
- any other member that notifies the TRIPS Council of its intention to use the system. This is a one-time notification that can be made at any time, including together with the first detailed notification regarding specific needs addressed below. Certain members have agreed to opt out of using the system as importers¹²¹ while some others have agreed only to use the system as importers in situations of national emergency or other circumstances of extreme urgency.¹²²

(c) Exporting members

No restriction applies to the eligibility of members as exporting countries. But like compulsory licensing in general, the additional flexibility under the special compulsory licensing system is optional, and therefore no member is obliged to implement the system in its domestic legislation.

(d) Notifications

Certain notifications to the TRIPS Council by both importing and exporting members are required as a prerequisite for the use of the system.¹²³ These notifications are for information purposes and do not require approval by any WTO body before the special compulsory licensing system can be used. They can be accessed in the three official WTO languages (English, French and Spanish) on a dedicated web page, www.wto.org/phnotifs.

Apart from the one-time notification by eligible importing members mentioned in (b) above, members are to notify certain information each time they want to use the system. These details are set forth in paragraph 2(a) of the Annex to the TRIPS Agreement:

- the names and expected quantities of the product(s) needed;
- confirmation that the eligible importing member in question has established, in one of the ways set out in the Appendix to the Annex, that it has insufficient or no manufacturing capacity in the pharmaceutical sector for the product(s) in question. The Chairman's statement calls for the notification to include information on how

¹²¹ Namely Australia; Canada; the European Communities with its member States; Iceland; Japan; New Zealand; Norway; Switzerland; and the United States (see footnote 3 to paragraph 1b) of the Annex to the TRIPS Agreement).

¹²² Namely Hong Kong, China; Israel; Korea; Kuwait; Macao, China; Mexico; Qatar; Singapore; Chinese Taipei; Turkey; and the United Arab Emirates (see Chairman's Statements in WTO documents [WT/GC/M/82](#) and Corr.1, paragraph 30 and [WT/GC/M/100](#) and Corr.1, paragraph 30).

¹²³ A guide to notifications, including a set of model notifications, is available at: www.wto.org/medicinesnotifications.

this assessment has been established. LDCs are deemed to have insufficient or no manufacturing capacities and are therefore automatically exempted from this requirement; and

- where a pharmaceutical product is patented in the territory of the member concerned, confirmation that it has granted or intends to grant a compulsory licence in accordance with Articles 31 and 31*bis* and the provisions of the Annex.

In response to the notification of the specific needs made by the importing member, the exporting member is to notify the TRIPS Council of the grant of the exporting country's compulsory licence and the conditions attached to it (see (e) below), the details of the licence (the name and address of the licensee; the product(s) involved; the quantity or quantities to be produced under the licence; the designated importing country or countries; and the duration of the licence), and the website address where the licensee is required to post the information, before shipment takes place, of the quantities being supplied to each destination and the distinguishing features of the product(s).

(e) Safeguards against diversion

During the preparatory work leading to the establishment of the special compulsory licensing system, concerns were expressed about the potential risk of diversion of pharmaceutical products to be manufactured under the system. With a view to ensuring that such products are used for the public health purposes underlying their importation into the eligible importing member, it was agreed that specific safeguards against diversion would be required in addition to the above provisions ensuring transparency of the operation of the system and establishing certain notification requirements.

For this purpose, exporting members must attach the following conditions to the compulsory licence (Annex to the TRIPS Agreement, para. 2(b)):

- only the amount necessary to meet the needs of the eligible importing member can be manufactured under the licence;
- the entirety of the production must be exported to the member which has notified its needs to the TRIPS Council; and
- products manufactured under the special compulsory licensing system must be clearly identified as such through specific labelling or marking. Suppliers should distinguish the products through special packaging and/or special colouring or shaping of the products – provided that these distinguishing characteristics are feasible and do not have a significant impact on price.

Paragraph 3 of the Annex to the TRIPS Agreement obliges importing members to take measures to prevent the re-exportation of the products concerned. Several qualifiers

apply to this requirement, namely that the measures must be reasonable, within the means of the member concerned and proportionate to its administrative capacities and to the risk of trade diversion.

In addition, in order to counter the risk of the importation and sale of any diverted products produced under the system in their territories, all members are required to make available the legal means which have to be put at the disposal of the right holder in any event under the TRIPS Agreement; in other words the normal enforcement procedures and remedies in the event that the product is patent-protected in that jurisdiction (Annex to the TRIPS Agreement, para. 4).

(f) Avoidance of double remuneration

Where patents on the needed medicines exist in both the importing and the exporting country and two compulsory licences are granted, the basic rule in Article 31(h) would require that adequate remuneration be paid in both countries to the right holder.

However, with a view to avoiding double remuneration of the patent owner for the same product consignment, the special compulsory licensing system derogates from the obligation of the importing country under Article 31(h) with respect to products for which remuneration has already been paid in the exporting member. The derogation also specifies that the remuneration in the exporting member is to be calculated taking into account the economic value of the use in the importing member (Article 31*bis*.2).

(g) The special case of regional trade agreements

A developing country or LDC may export pharmaceutical products manufactured or imported under a compulsory licence, notwithstanding the obligation under Article 31(f) to the extent that it is a party to an RTA and the following conditions are met (Article 31*bis*.3):

- the RTA complies with GATT Article XXIV and the Decision of 28 November 1979 on Differential and More Favourable Treatment Reciprocity and Fuller Participation of Developing Countries¹²⁴ (also called the 'Enabling Clause');
- at least half of the RTA members are LDCs listed as such by the United Nations; and
- the exporting country and the country needing the product manufactured or imported under a compulsory licence share the public health problem in question.

The purpose of this derogation is to respond to concerns expressed by some developing countries, in particular those with smaller markets, about not being in a position to effectively attract generic suppliers to produce medicines for their populations and to enable such countries to better harness economies of scale for the

¹²⁴ GATT document [L/4903](#).

purposes of enhancing purchasing power for, and facilitating the local production of, pharmaceutical products.

While the derogation facilitates export from one RTA member to another, it does not remove any need to grant a compulsory licence to cover the import of a medicine into other RTA members, if the medicine in question is patent-protected in those members. This is the logical consequence of the territorial application of national patents in the absence of regional patents. This aspect is also recognized by a provision that calls for the promotion of regional patent systems (Annex to the TRIPS Agreement, para. 5).

4 *Chairman's statements*

As mentioned above, the 2003 Decision and the 2005 Protocol were both adopted in the light of similar General Council Chairman's statements read prior to their adoption.¹²⁵ They respond to the concerns that the mechanism they established was too open-ended and might be abused in a way that would undermine the benefits of the patent system. For this purpose, each statement:

- recognizes that the system should be used in good faith to protect public health and should not be an instrument to pursue industrial or commercial policy objectives;
- addresses the concerns expressed relating to the risk of diversion by establishing that all reasonable measures should be taken to avoid diversion of the medicines from the markets for which they were produced; and
- sets out ways in which any differences arising from the implementation of the system can be settled expeditiously and amicably.

The statements also note that developed countries have agreed to opt out of using the system as importers; those members are listed in footnote 3 to paragraph 1b) of the Annex to the TRIPS Agreement. In addition, they record that 11 other members have agreed to use the system, as importers, only in situations of national emergency or other circumstances of extreme urgency. See section C3(b) above.

The Chairman's statement read out prior to the adoption of the 2005 Protocol further set out that the fact that non-violation complaints are considered non-applicable in this context under paragraph 4 of Article 31*bis* would be without prejudice to the overall question of the applicability of such complaints to the TRIPS Agreement.

5 *Domestic implementing legislation*

Accepting the 2005 Protocol is distinct from implementing the system in a member's domestic legal framework. The additional flexibilities made available under the special compulsory licensing system are optional, not mandatory. To take advantage of them,

¹²⁵ [WT/GC/M/82](#) and Corr.1, paras. 29-31; [WT/GC/M/100](#) and Corr.1, paras. 29-32.

a significant number of WTO members, including the vast majority of countries with export capacities in the pharmaceutical sector, have adopted domestic implementing laws or regulations that incorporate the system into their respective legal frameworks. Among the WTO members with implementing laws or regulations, three categories can be observed, i.e. (i) those members that have implemented the system to act exclusively as exporters; (ii) those members that have implemented the system to act exclusively as importers; and (iii) those members that have put in place laws or regulations allowing them to act both as exporters or importers under the system.¹²⁶ The adoption of such legislation follows the normal domestic legislative and regulatory processes and is distinct from the acceptance of the 2005 Protocol.

6 Use of the system

As regards the experience on the special compulsory licensing system's operation so far, one case of use has been reported to the TRIPS Council. In July 2007, Rwanda notified the TRIPS Council of its intention to import a pharmaceutical product from Canada under the system pursuant to paragraph 2(a) of the 2003 Decision.¹²⁷ In response, Canada issued a compulsory licence, under its Access to Medicines Regime, to a domestic pharmaceutical manufacturer in October 2007, authorizing the manufacture of a fixed-dose combination medicine for the treatment of HIV/AIDS infection for export to Rwanda under the system. This was notified to the TRIPS Council in accordance with paragraph 2(c) of the 2003 Decision.¹²⁸ Shipments of the medicine in question took place in September 2008 and 2009.¹²⁹

7 Review of the system's functioning

According to paragraph 7 of the Annex to the amended Agreement and paragraph 8 of the 2003 Decision, the TRIPS Council is to annually review the functioning of the system with a view to ensuring its effective operation. Since 2004, a report to the General Council has been prepared every year.¹³⁰ While earlier reviews were fairly short, more thorough debates have taken place in the TRIPS Council since 2009. Beyond the question of the operation of the system itself, broader issues, in particular as regards any alternatives to the use of the system to achieve the objective of access to medicines, procurement policies, and other related aspects affecting access to medicines, have also been raised.

¹²⁶ An overview of national implementing legislation notified to the TRIPS Council is available at: www.wto.org/sclsystemlaws. For an extended discussion of certain members' implementing legislation, see Roger Kampf, 'Special Compulsory Licences for Export of Medicines: Key Features of WTO Members' Implementing Legislation', WTO Staff Working Paper ERSD-2015-07 of 31 July 2015, available at: www.wto.org/english/res_e/reser_e/ersd201507_e.pdf.

¹²⁷ IP/N/9/RWA/1.

¹²⁸ IP/N/10/CAN/1.

¹²⁹ IP/C/W/526. See 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, Box 4.15, p. 178, for further discussion of Rwanda and Canada's use of the system.

¹³⁰ The annual reports can be accessed at www.wto.org/tripshealth. For the latest report as of this writing, see IP/C/84 (2019).

In the discussions, some members raised concerns about the system's functioning and considered it to be too complex and bureaucratic. In their view, the system did not represent the expected effective and expeditious solution to public health problems encountered by developing countries. According to these countries, the system's inadequacy is evidenced by its limited use. Some other members have argued that the shipments of medicines from Canada to Rwanda had demonstrated that the system could operate effectively. They further argue that the success of the system should not be measured in terms of the number of compulsory licences granted, but whether it had contributed towards better access to affordable medicines. In their view, there may have been less need to use the system due to other measures taken to enhance access to medicines, including through improved international procurement, increased donations of free medicines and lower prices often provided by right holders.

The broader picture of the debate on access to medical technologies and innovation is discussed in Module XI.