

## *Module IX*

### **TRIPS AND PUBLIC HEALTH**

#### **A. INTRODUCTION**

This module provides an overview of work done in the WTO on IP and public health. Module X briefly covers important work done in this area outside the WTO, notably in the WHO.

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 countries to take various kinds of measures to qualify or limit IPRs for public health purposes as well as in other respects. 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 Members' national laws already provide sufficient flexibility. Further, the TRIPS Agreement – and the IP system more generally – is only one element of the bigger challenge of access to medicines, which also includes such important factors as the public health system in general, drug regulatory authorities, financing, including insurance, infrastructure, procurement regimes and import tariffs applied to pharmaceutical products.

The importance of creating a positive, mutually reinforcing link between the IP system and access to medicines was explicitly recognized at the WTO's Fourth Ministerial Conference in Doha, Qatar, in November 2001, when Ministers adopted a Declaration on the TRIPS Agreement and Public Health ("the Declaration"). The Declaration responded to concerns that had been expressed about the possible implications of the TRIPS Agreement for public health, in particular access to patented medicines. The text of the Declaration is provided in Annex 6.

The TRIPS provisions pertinent to public health, especially those relating to patents and undisclosed information, have already been set out in preceding modules. This section discusses the flexibilities within the TRIPS Agreement that are most relevant to public health, and the way in which they were clarified and further developed by the Declaration and the so-called Paragraph 6 System.

#### **B. DOHA DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH**

##### **1. Concerns that triggered the discussions**

The TRIPS Agreement was negotiated to ensure that countries 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 flexibility 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 governments 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 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 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 Declaration is not limited to the diseases that are explicitly mentioned here, 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 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.

In addition, the 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. These important declarations signal an acceptance by all Members that they will not seek to prevent other Members from using these flexibilities.

Furthermore, it highlights the importance of the objectives and principles of the TRIPS Agreement for the interpretation of its provisions. Although the Declaration does not refer specifically to Articles 7 and 8 of the TRIPS Agreement, it refers to "objectives" and "principles", words that are the titles of these two articles respectively. See also the explanation in Module I, section B.1.

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 Declaration recognizes the importance of IP protection for the development of new medicines, while also noting the concerns about the effects of intellectual property protection on prices.

## **4. Clarification of flexibilities**

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

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 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.

In regard to the exhaustion of IPRs, which impinges on a Member's right to permit parallel imports, 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 Declaration clarifies that the effect of this and other 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, for example, between national, regional or international exhaustion. Under national exhaustion, a right holder can prevent importation of 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 B.5. and Box IX.1.

## **5. Transfer of technology**

The 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 D.3.

### **Box IX.1 TRIPS flexibilities as recognized 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).
- Freedom for each Member to establish its own regime for exhaustion without challenge, subject to the principle of non-discrimination.

## **6. Follow-up**

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

- Based on the Declaration, a TRIPS Council Decision (IP/C/25) extended the transition period for LDCs 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 Council (WT/L/478) waived the otherwise applicable provision on exclusive marketing rights in Article 70.9 for the same period. This specific extension of the transition period applying to pharmaceutical products is in addition to the general extension of the transition period given to LDCs for the implementation of the TRIPS Agreement by July 2013 (IP/C/40). These two decisions are provided Annexes 9 and 10.
- Following the instruction given by the 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 the so-called Paragraph 6 System, waiving certain obligations under the TRIPS Agreement. The Paragraph 6 System is explained in the next section.

## **C. PARAGRAPH 6 SYSTEM**

### **1. The issue**

The Declaration recognized the problem of countries with insufficient or no manufacturing capacities in the pharmaceutical sector in making effective use of compulsory licensing, and instructed the Council for TRIPS to find an 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 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 third 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 capacities became obligated to provide patent protection for pharmaceutical products pursuant to the special transition arrangements in Article 65.4.

### **2. The solution: establishment of the Paragraph 6 System**

This problem was recognized in paragraph 6 of the Declaration (hence the reference to the "Paragraph 6 System"). Subsequent work in the TRIPS Council prepared the ground for the adoption of two important General Council decisions establishing the Paragraph 6 System, which were both adopted in the light of a Chairman's statement setting out several key shared understandings of Members on how the Paragraph 6 System would be interpreted and implemented. These two decisions are provided in Annexes 7 and 8.

For this purpose, the General Council Decision of 30 August 2003 on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health (WT/L/540 and Corr.1) waives 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 that the waivers contained in the 2003 Decision are of a temporary nature, 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 was reached on 6 December 2005 when the General Council adopted a Protocol Amending the TRIPS Agreement (WT/L/641) in the light of a chairman's statement along the lines accepted in August 2003.

The 2005 Protocol is the first amendment of any WTO Agreement to be agreed to by WTO Members since the WTO Agreement came into force in 1995. It closely tracks the text of the 2003 Decision. No substantive changes were made to the original Paragraph 6 System implemented by the waiver Decision of 2003. It was submitted to Members for acceptance and requires acceptance by two-thirds of the Members to enter into force, which had not yet occurred as of the time of writing.<sup>1</sup>

Accepting the Protocol is clearly distinct from implementing the Paragraph 6 System in Members' domestic legal frameworks. In other words, the Protocol can be accepted independently from adopting domestic implementing legislation, and vice-versa. Accepting the Protocol is a legal act whereby a Member expresses its consent to be bound by the Protocol at the international level, or, in other words, its consent that all WTO Members are *entitled* — that is permitted but not required — to use the Paragraph 6 System, which is incorporated in the TRIPS Agreement through the agreed amendment. This process of acceptance needs to follow the relevant Member's own constitutional requirements.<sup>2</sup> Should a WTO Member wish to make use of the additional flexibilities provided in the Protocol, it may need to implement laws or regulations following its normal domestic legislative and regulatory processes.

The waiver provisions of the 2003 Decision immediately came into effect on 30 August 2003 and remain applicable until the date on which the TRIPS amendment takes effect for a Member. Given that the content of the August 2003 Decision and the proposed amendment of the TRIPS Agreement is the same, the substance of the legal regime applying to Members will remain the same, whether they have accepted the Protocol or not.

### **3. Description of the System**

The Paragraph 6 System established under the 2003 Decision and the 2005 Protocol 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 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 Paragraph 6 System and to ensure that only countries with insufficient domestic capacity import under it. It also

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<sup>1</sup> A list of countries which have notified their acceptance to the WTO is available at the following website: [http://www.wto.org/english/tratop\\_e/trips\\_e/amendment\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/amendment_e.htm)

<sup>2</sup> More information on how to accept the Protocol Amending the TRIPS Agreement, including a model instrument of acceptance, is available at:

[http://www.wto.org/english/tratop\\_e/trips\\_e/accept\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/accept_e.htm)

provides for safeguards against the diversion of products to markets for which they are not intended;

- 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;
- 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.

(a) Scope and coverage

The Paragraph 6 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 Declaration, including active ingredients necessary for their manufacture and diagnostic kits needed for their use.

(b) Eligible importing Members

The following Members qualify as eligible importing countries:

- LDCs, which are automatically eligible to import under the Paragraph 6 System;
- any other Member that notifies the TRIPS Council of its intention to use the Paragraph 6 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. Note, however, that:
  - certain Members have agreed to opt out of using the Paragraph 6 System as importers (full opt-out countries): Australia; Austria; Belgium; Canada; the Czech Republic; Cyprus; Denmark; Estonia; Finland; France; Germany; Greece; Hungary; Iceland; Ireland; Italy; Japan; Latvia; Lithuania; Luxemburg; Malta; the Netherlands; New Zealand; Norway; Poland; Portugal; the Slovak Republic; Slovenia; Spain; Sweden; Switzerland; the United Kingdom and the United States;
  - certain other Members have agreed to only use the Paragraph 6 System as importers in situations of national emergency or other circumstances of extreme urgency (partial opt-out countries): Hong Kong, China; Israel; Korea; Kuwait; Macao, China; Mexico; Qatar; Singapore; Chinese Taipei; Turkey; and the United Arab Emirates.

(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 Paragraph 6 System is optional, and therefore no Member is obliged to implement the Paragraph 6 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 Paragraph 6 System.<sup>3</sup> These notifications are for information purposes and do not require approval by any WTO body before the Paragraph 6 System can be used. They can be accessed in the three official WTO languages (English, French, and Spanish) on a dedicated webpage.<sup>4</sup>

Apart from the one-time notification by eligible importing Members mentioned in (b) above, they are to notify certain information each time they want to use the Paragraph 6 System. These details are:

- 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 Annex to the Decision, 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 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 Article 31 and the provisions of the Paragraph 6 System.

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 Paragraph 6 System, concerns were expressed about the potential risk of diversion of pharmaceutical products to be manufactured under the Paragraph 6 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 Paragraph 6 System and establishing certain notification requirements.

For this purpose, exporting Members must attach the following conditions to the compulsory licence:

- only the amount necessary to meet the needs of the eligible importing Member can be manufactured under the licence;

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<sup>3</sup> A set of model notifications is available at: [www.wto.org/english/tratop\\_e/trips\\_e/trips\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/trips_e.htm)

<sup>4</sup> Available at: [http://www.wto.org/english/tratop\\_e/trips\\_e/public\\_health\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/public_health_e.htm)

- 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 Paragraph 6 System must be clearly identified as such through specific labelling or marking. Suppliers are to 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.

Importing Members are 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 Paragraph 6 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.

(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 Paragraph 6 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.

(g) The special case of regional trade agreements

A developing 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:

- 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 Countries (L/4903) (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 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 the Paragraph 6 System that explicitly calls for the promotion of regional patent systems.

#### **4. Chairman's statement**

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. The statement was designed to respond to the concerns that the Decision was too open-ended and might be abused in a way that would undermine the benefits of the patent system. For this purpose, the statement:

- recognizes that the Paragraph 6 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 adequately.

The statement also notes that 33 developed countries have agreed to opt out of using the Paragraph 6 System as importers. In addition, the statement records that 11 other Members agreed to use the Paragraph 6 System, as importers, only in situations of national emergency or other circumstances of extreme urgency.

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

#### **5. Domestic implementing legislation**

The additional flexibilities made available under the Paragraph 6 System are optional, not mandatory. To take advantage of them, a number of WTO Members have adopted domestic implementing laws or regulations that incorporate the Paragraph 6 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 Paragraph 6 System to act exclusively as exporters, (ii) those Members that have implemented the Paragraph 6 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 Paragraph 6 System.<sup>5</sup> As explained in section C.2 above, the adoption of such legislation follows the normal domestic legislative and regulatory processes and is distinct from the acceptance of the Protocol Amending the TRIPS Agreement.

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<sup>5</sup> An overview of national implementing legislation notified to the TRIPS Council is available at: [http://www.wto.org/english/tratop\\_e/trips\\_e/par6laws\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/par6laws_e.htm). Additional information on certain Members' implementing legislation can also be found in Section 2 of the Annex to the TRIPS Council's 2010 Report to the General Council on the Annual Review of the Paragraph 6 System (IP/C/57).

## **THE PARAGRAPH 6 SYSTEM IN A NUTSHELL**

### **The scenario**

The Paragraph 6 System is not intended to cater as a panacea for procuring medicines, but addresses a particular problematic scenario that was identified in the Doha Declaration. The System provides a specific legal avenue for an eligible WTO Member to procure medicines in the following circumstances:

- an eligible Member wants to import a pharmaceutical product, which it cannot produce locally, from a generic producer in another WTO 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 (or where the non-predominant part of production under a compulsory license if issued already in the exporting Member cannot meet the needs of the importing Member)

### **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 Paragraph 6 System (other than a 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 a 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 Paragraph 6 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 Paragraph 6 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.

## **6. Use of the Paragraph 6 System**

As regards the experience on the Paragraph 6 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 Paragraph 6 System pursuant to paragraph 2(a) of the Decision<sup>6</sup>. 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 Paragraph 6 System. This was notified to the TRIPS Council in accordance with paragraph 2(c) of the Decision. Shipments of the medicine in question took place in September 2008 and 2009.<sup>7</sup>

## **7. Review of the Paragraph 6 System's functioning**

According to paragraph 8 of the 2003 Decision, the TRIPS Council is requested to review annually the functioning of the Paragraph 6 System with a view to ensuring its effective operation. Since 2004, a report to the General Council has been prepared every year.<sup>8</sup> While earlier reviews were fairly short, more thorough debates have taken place in the TRIPS Council since October 2009. Beyond the question of the operation of the Paragraph 6 System itself, the broader issues, in particular as regards any alternatives to the use of the Paragraph 6 System to achieve the objective of access to medicines, procurement policies, and other related aspects affecting access to medicines, have also been raised.

In the discussions, some Members raised concerns about the Paragraph 6 System's functioning and considered it to be too complex and bureaucratic. In their view, the Paragraph 6 System did not represent the expected effective and expeditious solution to public health problems encountered by developing countries. According to these countries, the Paragraph 6 System's inadequacy is evidenced by its limited use, as well as by the still relatively small number of acceptances of the Protocol. Some other Members have argued that the shipments of medicines from Canada to Rwanda had demonstrated that the Paragraph 6 System could operate effectively. They further argue that the success of the Paragraph 6 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.

## **D. ACCESS TO MEDICINES: THE BROADER PICTURE**

While emphasizing the scope in the TRIPS Agreement available for Members to tailor their domestic implementation with a view to promoting access to medicines, the Doha Declaration stresses the need for the Agreement to be "part of the wider national and international action to address these problems". It is generally accepted that there is a need for a broad-based approach to access to medicines, which should include dimensions such as innovation, access and funding. Other policies affecting access to medicines that have regularly been referred to in recent discussions include (i) transparent, competitive and non-discriminatory procurement procedures and practices; (ii) effective competition policies; (iii) the need to ensure the safety, quality and efficacy of medicines; (iv) the elimination of tariffs and

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<sup>6</sup> IP/N/9/RWA/1.

<sup>7</sup> IP/N/10/CAN/1.

<sup>8</sup>The annual reports can be accessed at:

[http://www.wto.org/english/tratop\\_e/trips\\_e/pharmpatent\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/pharmpatent_e.htm). The latest and most comprehensive report so far is contained in WTO Document IP/C/57 and Corr.1.

taxes; and (v) the need to have a sound health care infrastructure in place. It has also been emphasized that alternative funding mechanisms, donations, partnership programmes and licensing agreements, as well as the increased application of tiered-pricing schemes by pharmaceutical companies have contributed to a positive change regarding access to medicines.

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

The broader issues have fostered cooperation between the three intergovernmental organizations with key responsibilities in this area, namely the WHO, WIPO and WTO. This cooperation was initially framed by the Doha Declaration and has now led to an intensified process of trilateral cooperation, which also includes the implementation of the WHO's Global Strategy and Plan of Action. This partnership between the three organizations builds on the complementary roles of each organization and takes into account the different nature of their respective mandates and priorities. As a concrete result, the three organizations have initiated a series of joint technical symposia addressing issues at the intersection of public health, trade and IP. The symposia are designed to provide a platform for the discussion of current issues and the exchange of information and experiences. They are expected to enhance the dialogue between the relevant organizations and other key stakeholders, and foster the mutual understanding of public health and IP policy. In July 2010, the first symposium addressed "*Access to Medicines: Pricing and Procurement Practices*" and, in February 2011, the second symposium provided an opportunity to review issues related to "*Access to Medicines, Patent Information and Freedom to Operate*".<sup>9</sup>

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<sup>9</sup> Presentations and background information from the symposia are available at: [http://www.wto.org/english/news\\_e/news10\\_e/trip\\_16jul10\\_e.htm](http://www.wto.org/english/news_e/news10_e/trip_16jul10_e.htm) and [http://www.wto.org/english/news\\_e/news11\\_e/trip\\_18feb11\\_e.htm](http://www.wto.org/english/news_e/news11_e/trip_18feb11_e.htm) A joint study on 'Promoting Access and Medical Innovation: Intersections between Public Health, Intellectual Property and Trade' will be published in 2012. More information on the trilateral cooperation is available at [www.wto.org/english/tratop\\_e/trips\\_e/who\\_wipo\\_wto\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/who_wipo_wto_e.htm)