

**IMPLEMENTATION OF THE WTO
GENERAL COUNCIL DECISION
ON PARAGRAPH 6 OF THE
DOHA DECLARATION ON THE
TRIPS AGREEMENT AND
PUBLIC HEALTH**

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While participants in the review process had differing perspectives, there was general consensus among them that the general approach adopted in the paper is appropriate – that the interpretation and definition of provisions in the WTO General Council Decision on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health should facilitate the public health objective of ensuring access to medicines.

Any views expressed are the views of the author and do not necessarily reflect the views of the World Health Organization (WHO). The author is solely responsible for the opinions expressed herein.

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Introduction

Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health,¹ adopted at the Fourth World Trade Organization (WTO) Ministerial Conference (9-14 November 2001), instructed the WTO Council for TRIPS (Trade-Related Aspects of Intellectual Property Rights) to address how WTO Members lacking or with insufficient manufacturing capacities in pharmaceuticals can make effective use of compulsory licensing. Many developing countries and the least developed countries (LDCs) cannot produce either active ingredients or formulations, due to lack of technology, equipment, human resources or economic viability of domestic production. While these countries may issue compulsory licences to import generic versions of patent-protected medicines, TRIPS rules impose constraints on the ability of countries to authorize exports of such products. Paragraph 6 promised a solution to the export problem caused by these constraints.

Currently, some developing country Members of WTO do not yet provide patent protection for pharmaceutical products. Some companies in these countries produce generic versions of pharmaceuticals at prices significantly lower than those offered by brand name companies. Those products may legally be exported freely to other countries, provided that a) they are not covered by patents in the importing country; or b) if the product is patent protected in the importing country, that a compulsory licence is granted there. The problem is that, as product patents for pharmaceuticals become enforceable in accordance with the TRIPS Agreement,² countries with industrial and export capacity will face legal obstacles to produce and export cheap generic copies of patented medicines.

If a product is deemed covered in an exporting country by the exclusive rights granted to the patent owner, production for export could take place under a compulsory licence.³ However, the TRIPS Agreement establishes that, unless a compulsory licence is granted to remedy anti-competitive practices (Article 31 (k)), it must "predominantly" supply the licensee's domestic market (Article 31 (f)). This means that if a company received a request to manufacture and export a product that is covered in the manufacturing country by a third party's patent, it would not be able to do so (in the absence of patent owner authorization), to the extent that production were predominantly for export and not for the manufacturer's domestic market.

¹ WT/MIN(01)/DEC/2, 20 November 2001, hereinafter "the Doha Declaration".

² By 2005 at the latest, all WTO Members (except least developed countries) must provide patent protection for pharmaceutical products.

³ Production for export, however, may be deemed admissible under Article 30 of the TRIPS Agreement. See, e.g. Commission on Intellectual Property Rights, *Integrating Intellectual Property Rights and Development Policy*, London, 2002, available on the Internet at www.iprcommission.org; Correa C, *Implications of the Doha Declaration on the TRIPS Agreement and Public Health*, Geneva, WHO, Health Economics and Drugs, EDM Series No. 12, 2002.

As a result of these legal constraints and, although countries without sufficient manufacturing capacity in pharmaceuticals could issue a compulsory licence for the importation of products they cannot manufacture, they will not be able to find export sources of affordable new medicines.

The Doha Declaration directed the Council for TRIPS "to find an expeditious solution to this problem and to report to the General Council before the end of 2002". An agreement to address the problem was finally reached on 30 August 2003,⁴ based on a compromise developed by the Chair of the TRIPS Council⁵ and on a "Statement" by the Chair of the General Council⁶ that "represents several key shared understandings of Members regarding the Decision to be taken and the way in which it will be interpreted and implemented".

This paper examines the ways in which the Decision can be implemented in prospective importing and exporting countries. It is addressed to policy-makers and to potential suppliers and purchasers of pharmaceutical products.⁷ The analysis is motivated by a desire to serve a number of public health objectives, namely the need to ensure:

- a rapid and effective response to public health needs;
- equality of opportunities for countries in need, irrespective of the patent status of a drug in the importing country, and without regard to its membership in the WTO;⁸
- the sustainability of quality supply at affordable prices;
- the facilitation of a multiplicity of potential suppliers, both from developed and developing countries, which can compete to drive prices down; and
- provision of a wide range of pharmaceutical products to meet an array of health problems.

In implementing the Decision it should also be borne in mind that the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being, as defined in the Constitution of the World Health Organization.⁹ Progressive realization of that right involves access to health facilities, care, treatment and support, including access to affordable medicines.¹⁰

⁴ See WT/L/540, available on the Internet at www.wto.org (hereinafter "the Decision"). The Decision is reproduced in Annex 1.

⁵ See the text of the Statement by the Chairman of the Council for TRIPS of 16 December 2002 (JOB(02)/217).

⁶ See WT/GC/M/82, para. 29, available on the Internet at www.wto.org.

⁷ Importation under the Decision may be undertaken by governments as well as by nongovernmental organizations (NGOs), public or private hospitals, companies and other entities.

⁸ There is a significant number of countries which are not members of the WTO (while many are negotiating accession) that may face the problems addressed in paragraph 6.

⁹ For a description of the sources and scope of the right to health, see Report of the Special Rapporteur of the Commission on Human Rights on *The right of everyone to the enjoyment of the highest attainable standard of physical and mental health*, E/CN.4/2003/58, 13 February 2003, para. 10–36.

¹⁰ As interpreted by the Committee on Economic, Social and Cultural Rights (CESCR), access to essential medicines constitutes a core element of the right to the highest attainable standard of health under the International Covenant on Economic, Social and Cultural Rights. See CESCR General Comment 14 (E/C.12/2000/4), para. 43.

This paper proceeds according to the following plan:

The first section details the legal status of the Decision and the circumstances in which the Decision may be used. This section considers amendments to national laws needed to implement the Decision; the circumstances in which the Decision may be invoked; the products covered by the Decision; the countries which may use the Decision; and the purposes for which Members may use the Decision.

The second section considers the steps that an importing country must undertake to employ the Decision. These include required notifications to the TRIPS Council and confirming its intent to issue a compulsory licence.

The third section considers the steps required of an exporting country. These include issuance of a compulsory licence and required notifications by the exporting supplier and the exporting country.

The next section reviews the obligations on an importing country to take measures to prevent diversion of imported goods to other markets once it has employed the system.

A further section discusses the issue of suspension of the system.

A brief concluding section is followed by an annex summarizing the context and steps required to use the system established by the Decision.

Circumstances in which the Decision may be used

Legal status of the Decision

The Decision adopted by the WTO General Council implements interim waivers with regard to the obligations set out in paragraphs (f) and (h) of Article 31 of the TRIPS Agreement. The Council for TRIPS shall review annually the functioning of the system set out in this Decision "with a view to ensuring its effective operation and shall annually report on its operation to the General Council" (paragraph 8). This waiver shall terminate on the date on which an amendment to the TRIPS Agreement replacing its provisions takes effect for a Member.¹¹ The TRIPS Council was mandated to initiate, by the end of 2003, work on the preparation of such an amendment with a view to its adoption within six months, "on the understanding that the amendment will be based, where appropriate, on this Decision" (paragraph 11).

The Decision does not affect the use of the flexibilities allowed by the TRIPS Agreement, including the adoption of other avenues to facilitate the export and importation of cheaper pharmaceutical products, such as on the basis of Article 30 of the TRIPS Agreement.¹²

Amendment to national laws

A waiver does not imply any change of substantive treaty obligations; it only temporarily suspends their operation (Article 57 of the Vienna Convention on the Law of Treaties). A WTO waiver means that a Member shall not initiate a complaint against another Member if the latter acted under the terms of the adopted waiver. However, to the extent that a Member's national law is not revised to implement the terms of the waiver,¹³ patent owners may invoke provisions in the national law to block the export of a patented drug by other companies. Whether generic drug makers will actually be able to export under the terms of the Decision, therefore, will depend on the extent to which national laws allow for it.

¹¹ The purpose of this linkage has been to provide legal certainty and encourage countries to implement the Decision as soon as possible. So far, only a handful of countries are reported to have taken action in order to amend national laws and allow exports under the Decision.

¹² According to para. 9, "This Decision is without prejudice to the rights, obligations and flexibilities that Members have under the provisions of the TRIPS Agreement other than paragraphs (f) and (h) of Article 31, including those reaffirmed by the Declaration, and to their interpretation. It is also without prejudice to the extent to which pharmaceutical products produced under a compulsory licence can be exported under the present provisions of Article 31 (f) of the TRIPS Agreement".

¹³ So far only two countries (Canada and Norway) have adopted legislative changes to implement the Decision. See Canada's Bill C-9, passed by the House of Commons on 4 May 2004, which amended the Patent Act and the Food and Drugs Act, and the amendment of 14 May 2004 to the Norwegian Regulations of 20 December 1996 No. 1162 relating to the patent act.

Under the adopted system, and in a manner fully consistent with the TRIPS Agreement, countries may grant a compulsory licence¹⁴ to import a patented drug. However, some developing countries provide for the granting of compulsory licences for the manufacture of patented subject matter, and not for importation. Hence, in order to make any solution under paragraph 6 operational, those developing countries would need to amend their compulsory licence laws to provide for importation.

The Decision does not waive the application of Article 31 (b) of the TRIPS Agreement, which requires that prior to granting a compulsory licence, licence applicants make efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and within a reasonable period of time. This requirement may be waived by national law in the case of a national emergency or other urgent circumstances or in cases of public non-commercial use. National laws may also determine that, in cases where Article 31 (b) cannot be waived and the Decision is to be applied, the period of time be shorter than in normal situations so as to expedite access to needed pharmaceutical products.¹⁵

Similarly, amendments to national laws will be necessary in the prospective exporting countries. Compulsory licences are granted under grounds specified in national laws. The supply of export markets is not an accepted ground in most national laws. Moreover, Article 31 (f) of the TRIPS Agreement requires that compulsory licences be issued "predominantly" for the domestic market. National laws in exporting countries must be amended to permit paragraph 6 compulsory licences exclusively to supply a foreign country.

The need to apply the Decision will arise when the patent owner does not agree to supply a patented pharmaceutical product to a country with insufficient or no manufacturing capacity in pharmaceuticals, at an affordable price or under other suitable conditions. Whatever humanitarian reasons¹⁶ underpin the country's demand for a given pharmaceutical product, nothing in the adopted system compels the patent owner to supply it or to forego the owner's rights under national laws.

¹⁴ As mentioned below, the Decision also applies in cases of government use for non-commercial purposes.

¹⁵ The Preamble of the Decision recognizes "where eligible importing Members seek to obtain supplies under the system set out in this Decision, the importance of a rapid response to those needs consistent with the provisions of this Decision".

¹⁶ See the Statement by the Chair of the General Council accompanying the Decision.

In this context, the patent owner may eventually exercise his rights to appeal a decision granting a compulsory licence in both the importing and exporting country. In some countries, such appeal may not suspend the immediate execution of the compulsory licence. In others, this may not be the case¹⁷ and the patent owner may obtain an injunction and thereby delay exports or imports under the compulsory licence until a final administrative or judicial decision is taken. National patents laws, hence, will have to be amended, as necessary, in order to allow for an effective and rapid application of the Decision to address public health needs, particularly in cases of national emergency or urgency. In undertaking such an amendment, prospective exporting and importing countries should both consider establishing a short period for fulfilling the obligation under Article 31 (b) of the TRIPS Agreement¹⁸ for a prior negotiation with the patent owner.¹⁹ Although Article 31 (b) has not been waived, as mentioned below, exporting countries may consider that compliance with Article 31 (b) should not be required when the importing country resorts to public non-commercial use or grants a compulsory licence on grounds of a national emergency or other circumstances of extreme urgency.

The waiver granted by the Decision with respect to payment of compensation in the importing country (Article 31 (h) of the TRIPS Agreement) may also need to be implemented through a legal revision, in order to prevent patent owners' potential claims of compensation according to the national law.

Implementation of the Decision may not only require making specific changes to national laws, but also ensuring that countries do not assume TRIPS-plus obligations under bilateral or regional treaties. Bilateral agreements established by the USA with some developing and developed countries (e.g. Australia, the Central American countries, Chile, Jordan, Morocco), for instance, require the protection of data under a sui generis regime of data exclusivity for at least five years from the date of the first approval of a pharmaceutical product in the country. Some bilateral agreements, moreover, establish "linkage" requirements, so that, without the consent and acquiescence of the patent owner, national health authorities are prevented from granting marketing approval for a generic product as long as a patent over the product is in force.

¹⁷ The experience of the Philippines is illustrative in this regard. One hundred and twenty petitions for compulsory licences were filed under the old Philippine patent law, out of which 51 compulsory licences were granted. However, the beneficiary companies were unable to market the products due to appellate proceedings that delayed the execution of the decision. The delay in the proceedings also led to the dismissal of 23 applications. Fourteen petitions were also dismissed due to a compromise agreement between the parties. Eight petitions were dismissed because the patent expired while the petitions were still pending. The only compulsory licence granted after the new Philippine Intellectual Property Code took effect on 1 January 1998 was a compulsory licence petition filed on 8 December 1991 when the old patent law was in effect. This petition was finally granted on 19 December 2001, i.e. after a period of ten years. The rest of the petitions filed under the old Philippine patent law are still pending (communication from Susan Villanueva, College of law, Philippines, 26 September 2003, on file with the author).

¹⁸ Since prior efforts to obtain a compulsory licence would have to be made, in some cases, both in the importing and exporting country, and given the need to provide a rapid response, coordination on this matter may be envisaged between the two countries.

¹⁹ Canadian Bill C-9 requires the applicant of the compulsory licence to provide a declaration showing that at least thirty days before filing the application it sought a voluntary licence from the patent owner on reasonable terms and that his effort were unsuccessful (section 21.04.3 (c)).

The implications of these obligations are quite significant, and may delay introduction of generic products, even where compulsory licences are issued. Under the data exclusivity terms, if a compulsory licence were granted in a country to import a pharmaceutical product, a generic company would have to develop on its own all the test data as required for approval. This is a very lengthy, costly, duplicative and wasteful process given that the data have already been generated by a brand-name company, and will create an enormous obstacle to the use of the Decision. Moreover, the "linkage" between patent protection and marketing approval seems to erect an almost insurmountable barrier to the execution of a compulsory licence or government non-commercial use, since the compulsory licensee or government would be authorized to use the patented invention but not to obtain the regulatory approval to make it available. Countries willing to use the Decision (as importers or exporters) would have to devise ways, including crafting specific exceptions, to overcome these restrictions.

Finally, it is to be noted that the implementation of the Decision through appropriate amendments to national laws, as necessary, should not be regarded as a matter of mere convenience or political choice. The Decision creates international obligations that must be complied with in good faith.²⁰ States' human right obligations are also relevant in this context for both importing and exporting countries. For instance, under the International Covenant on Economic, Social and Cultural Rights, the State parties' obligations to take steps towards the full realization of the right to health include: (a) a domestic obligation to fulfil the right to health, which requires States to adopt appropriate legislative and administrative measures towards the full realization of the right to health (General Comment No. 14, para. 33), and (b) an international obligation to take steps, individually and through international assistance and cooperation, especially economic and technical, towards the full realization of the rights recognized in the Covenant, including the right to the highest attainable standard of health (General Comment No. 14, paras 38–39).²¹

In sum, WTO Members should review their domestic laws in order to determine what amendments are required in order to implement the Decision, and undertake the necessary legal adaptations. Such review should consider the procedures for granting compulsory licences, in order to ensure their timely granting and that their execution could not be prevented by appeals or other legal actions.

²⁰ See Vienna Convention on the Law of Treaties (Article 26).

²¹ Thus, Paul Hunt, the Special Rapporteur of the Commission on Human Rights, issued a press release lauding the Canadian Bill as an example of the fulfilment of such obligation of international assistance and cooperation. See also E/CN.4/2004/49/Add.1, particularly the discussion of the impact of the 30 August 2003 Decision therein (para. 43).

Patent rights in force

The Decision will apply when the required pharmaceutical products are patented, at least in the exporting country.

Patents may be obtained not only in relation to active ingredients, but also in respect of formulations, pharmaceutical salts, isomers, polymorphs, combinations, manufacturing processes, etc. In some countries the new use of a known product may also be patented (as a "second indication"). There are cases in which an active ingredient is off-patent, but the pharmaceutical product that contains it, its method or manufacture or use, is patented, even many years after the expiration of the original patent. In other cases, a patent on the active ingredient may coexist (though not necessarily for exactly the same period) with many other patents on the product.

Whenever this is the case, the application of the Decision may require the granting of compulsory licences on a set of patents, not just on a single patent. If the coverage of the licence is not comprehensive, patent holders may complain that export or import of the product is not permitted.

Given the territoriality of the patent system and that the same patents are not necessarily applied for and obtained in all countries, and that the scope of the approved claims (with regard to the same invention) may also vary from country to country, the set of patents to be subject to compulsory licences may not be exactly the same in the exporting and importing countries. In addition, it will be necessary to determine whether the relevant patents are in force. They not only elapse due to the expiry of the term of protection, but also due to the lack of timely payment of maintenance fees.²²

Importing and exporting countries alike may overcome these problems by specifying that the compulsory licences apply to all patents on the product, its processes of manufacture and uses.

In what circumstances does the Decision apply?

The Decision may be applied when:

- a) the required pharmaceutical product is subject to one or more patents validly in force in the exporting country;
- b) the relevant patents are not subject in the exporting country to a compulsory licence to remedy anti-competitive practices that allows the licensee to export (Article 31 (k) of the TRIPS Agreement, in which case Article 31 (f) does not apply, and there is no need to employ the Decision waiver). Similarly, if a compulsory licence has been issued under which the licensee is predominantly supplying the domestic market, the licensee may supply an importing country with the non-predominant share of its production, and therefore without resort to the Decision waiver.

²² Most countries in the world provide for the automatic expiry of patents when the patent owner fails to pay the specified maintenance fees. Some laws allow for the rehabilitation of expired patents, but this is facultative (see Article 5 *bis* of the Paris Convention).

The Decision would be applicable whether or not the relevant products and processes are patented in the importing country.

If the required pharmaceutical product, or the process for its manufacture, is not patented in the importing country or the patent has expired or been revoked, there is no need to grant a compulsory licence in the importing country. But the Decision applies in order to allow the granting of such a licence in the exporting country.

A particular case may arise in LDCs, which can delay the recognition of pharmaceutical patents until 2016. LDCs that make use of this extension may consider granted pharmaceutical patents non-enforceable until that date. If, despite this possibility, patents on needed pharmaceutical products are enforced, they can grant compulsory licences to use the system set forth by the Decision.

If the product or process for its manufacture is patented in the importing country, then the importing country must issue a compulsory licence pursuant to the special conditions set forth in the Decision.

The Decision will not apply if the relevant product is off-patent in the exporting country, since a waiver of Article 31 (f) is not required. In this case, and if the product were patented in the importing country, a compulsory licence should only be granted in the importing country, under the ordinary terms allowed by the national law. There would be no need to comply with the special conditions established by the Decision.

Covered products

According to paragraph 1 (a) of the Decision, a "pharmaceutical product" is defined as "any patented product, or product manufactured through a patented process, of the pharmaceutical sector needed to address the public health problems as recognized in paragraph 1 of the Declaration". Several elements in this paragraph are important.

First, the Decision may apply either when a patent covers a product or a manufacturing process.

Second, it applies to products "of the pharmaceutical sector" in general, without any limitation as to the types of products (e.g. synthesized chemical products or biologicals), their characterization as essential medicines, or the kind of diseases they are intended to treat. The Decision clarifies that this concept includes "active ingredients necessary for its manufacture". The Decision may be applied in relation to a patent covering a pharmaceutical formulation or the process for its manufacture. The Decision also clarifies that "diagnostic kits needed for its use would be included". This wording may be interpreted as including reagents, diagnosis and monitoring kits. Microbicides can also be considered as covered products.

Vaccines are not specifically mentioned in the Decision. It may be argued that, had the drafters the intention to exclude them, an exception would have been expressly established. According to its ordinary meaning, "pharmaceutical"

means "of or engaged in pharmacy; of the use or sale of medicinal drugs".²³ Vaccines may be delivered at a pharmacy, are produced by pharmaceutical firms, and are crucial to address public health problems in developing countries. In view of the very purpose of the Declaration, the term "product ... of the pharmaceutical sector" should, hence, be read as including vaccines.²⁴

Third, the definition of pharmaceutical product refers to Paragraph 1 of the Declaration, which recognizes "the gravity of the public health problems afflicting many developing and least developed countries, *especially* those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics" (*emphasis added*). As the negotiation of the Decision made clear, it applies to pharmaceutical products for any disease. The three mentioned epidemics are only special cases – that certainly deserve particular attention – but the system established by the Decision is not limited to products related to them. Similarly, the Decision is not limited to "grave" diseases, since "gravity" in paragraph 1 of the Declaration is generally referred to "the public health problems" and is not intended to qualify the type of diseases to be addressed.

It is unclear whether a patent covering a therapeutic use (generally called "second indication") is covered by the Decision. The protected invention in this case is a method of treatment and not a product as such.²⁵ However, such patents can be effectively used to restrict access to the products for important therapeutic purposes. In the absence of an exception, and in view of the intended objectives of the Decision, it seems reasonable to interpret that the Decision can also be applied in these cases.

Which countries can use the system?

The Decision defines the "eligible importing Member[s]". They include:

- a) Any least developed country Member. The only qualification is that the LDC must be a WTO Member.
- b) Any other Member that has made a notification to the Council for TRIPS of its intention to use the system as an importer. As discussed below, the notification may be unqualified or qualified.

The Chair's Statement indicates that the following Members have agreed to opt out of using the system as importers: Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Japan, Luxembourg, the Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland, the United Kingdom and the United States of America. Until their accession to the European Union, the Czech Republic, Cyprus, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, the Slovak Republic and Slovenia agreed that

²³ *The Concise Oxford Dictionary*, p. 768.

²⁴ See, e.g. Vandoren P and Van Eeckhaute JC, The WTO Decision on Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, *The Journal of World Intellectual Property*, Vol. 6, No. 6, November 2003, p. 784.

²⁵ For instance, AZT – an important antiretroviral – was developed in the 1950s, and later on its use for HIV/AIDS was patented in many countries.

they would only use the system as importers in situations of national emergency or other circumstances of extreme urgency. These countries further agreed that upon their accession to the European Union, they would opt out of using the system as importers.

Other WTO Members have agreed that they would only use the system as importers in situations of national emergency or other circumstances of extreme urgency: Hong Kong, China; Israel; Korea; Kuwait; Macao, China; Mexico; Qatar; Singapore; the Separate Customs Territory of Taiwan, Penghu, Kinmen and Matsu; Turkey; and the United Arab Emirates.

For what purposes can the system be used?

LDCs can use the system to import pharmaceutical products under a compulsory licence granted according to any of the grounds authorized by their national laws. As the Doha Declaration has expressly confirmed, WTO Members are free to determine such grounds, which may include, inter alia, non-working, public interest, public health, remedying anti-competitive practices, emergency, and refusal to deal. It is clear that while a public health emergency may be one of the grounds for granting a compulsory licence, Member countries may invoke any other ground for that purpose.

The same applies to any other Member, except those Members who opt out of the system, or designate that they will use the system for limited purposes, such as in the case of national emergency.

A question arises as to the extent to which the wording in the Chair's Statement may limit the reasons for which a compulsory licence may be issued. The Statement indicates that the system "should be used in good faith to protect public health and, without prejudice to paragraph 6 of the Decision, not be an instrument to pursue industrial or commercial policy objectives".

At the same time, paragraph 7 of the Decision states that "Members recognize 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 Declaration". Paragraph 6 of the Decision aims at "harnessing economies of scale for the purposes of enhancing purchasing power for, and facilitating the local production of, pharmaceutical products" in the context of some regional trade agreements.

This wording suggests that industrial and commercial policy objectives should not be pursued by Member countries under the system established by the Decision, but that Members recognize such objectives cannot be excluded altogether. Thus, eligible importing Members may grant compulsory licences to foster the development of capacity in their pharmaceutical industry as a sustainable way to address their public health problems, for instance by importing active ingredients under the Decision for the local formulation of medicines.

Further, it seems clear that prospective suppliers of pharmaceutical products under the Decision include private companies, notably from countries where a strong generics industry has developed. Such companies will not make the needed investments nor bear the opportunity costs of supplying products under the Decision, unless they are able to obtain some commercial benefit.

Compulsory licence in the importing country

Notification of intention to use the system

Implementation of the Decision involves two kinds of notifications to the Council for TRIPS: a general notification about the intention to be an eligible importing Member, and a specific notification about the products, quantities, etc. that it intends to import.²⁶ This second type of notification is examined below. In both cases, "[t]hese notifications are for the sake of transparency and information only... [They] do not amount to authorization requests; Members concerned will not need to be approved by any WTO body in order to be able to use the system. They can automatically use the system once they have made the notifications".²⁷

The notification to the Council for TRIPS by a prospective importer Member is about the intention to use the Decision, and not about its actual use. This notification seems to be a condition to qualify as an "eligible importing Member". It is not a requirement for LDCs, however, which automatically qualify as eligible importing Members.

The notification may be unqualified, when the Member does not declare any limitations to its potential use of the system, or it may be qualified, when the Member voluntarily states that it will only use the system in a limited way. This limitation may be expressed in terms of the grounds of the compulsory licences (e.g. national emergency or other circumstances of extreme urgency) or otherwise. There is nothing in the Decision preventing a Member from changing, at any time, the terms of its notification. Thus, a Member that declared it would only make limited use of the system may later notify the TRIPS Council of its intention to expand its use.

The effect of the notification is declaratory. A Member can declare itself an "eligible importing Member". Footnote 2 of the Decision clarifies that this notification "does not need to be approved by a WTO body in order to use the system set out in this Decision". This means that neither the Council for TRIPS nor any other WTO body is entitled to review, approve or reject a notification and the specific terms under which it is made.

²⁶ Except as required by Article 31 (b), where applicable, there is no obligation to notify the patent owner about the intention to grant a compulsory licence and the conditions thereof. Likewise, there is no obligation to offer the patent owner the option to supply the required products under the terms and conditions established for the compulsory licence, as proposed in Canadian Bill C-56 (2003).

²⁷ Vandoren, Van Eeckhaute, *op. cit.*, p. 789.

Notification about needed products, compulsory licence

The second notification to be made by the eligible importing Member²⁸ relates to the importation of particular product(s).²⁹ It must include three elements:

Needed products

The would-be importing country is bound to notify the Council for TRIPS of:

- (i) the names of the needed product(s): the generic names of the required pharmaceuticals are to be mentioned;
- (ii) the "expected quantities": the notified quantities may not exactly correspond to the quantity of product finally requested or purchased. However, importing countries should carefully assess the quantities needed since, as mentioned below, the corresponding compulsory licence in the exporting country can be granted only for a specified amount.

The specification of quantities may be made in different ways. It may refer to the number of pills or other doses, to a quantity of active ingredients (e.g. 50 kilograms of drug X), to the number of patients to be treated over a period of time, or to other parameters.

The obligation to specify the expected quantity only applies to the notification. It does not refer to the specific terms of the compulsory licence. The compulsory licence issued in the importing country is not required to establish a determined quantity. The authorization could be given to import whatever is required over the duration of the compulsory licence. It would be too cumbersome for the importing country to issue a compulsory licence each time it needs to import a given quantity of a product.

A situation may arise in which the notified "expected" quantities may not correspond to the quantities effectively imported. A country may need, in particular, to import more than expected because it had underestimated its needs. This discord would not affect the right to import, so long as the compulsory licence was not limited to the amounts specified in the TRIPS Council notification.

The application of the Decision does not exclude the application of tendering procedures by the importing country. Moreover, there is no obligation on the importing country to determine a specific timeframe in which importation would take place.

²⁸ This notification also is for transparency purposes only and does not amount to an authorization request.

²⁹ "Joint notifications providing the information required under this subparagraph may be made by the regional organizations referred to in paragraph 6 of this Decision on behalf of eligible importing Members using the system that are parties to them, with the agreement of those parties" (footnote 4 of the Decision).

Establishing lack of or insufficient manufacturing capacity

This requirement does not apply to LDCs.

For other countries, the insufficient or no manufacturing capacity is not to be assessed in general, but for the particular pharmaceutical product(s) required.

There are two alternative ways to establish these circumstances, as set out in the Annex to the Decision:

- (i) The first option applies when the Member has established that it has no manufacturing capacity in the pharmaceutical sector.
- (ii) The second option applies when the Member has some pharmaceutical manufacturing capacity, has examined its capacity and found that, excluding any capacity owned or controlled by the patent owner, it is currently insufficient for the purposes of meeting its needs.

What manufacturing capacity means in either of the options is open to interpretation. In a market economy, pharmaceutical manufacturing capacity has two dimensions: technical capability (dependent on availability of technology, trained personnel, equipment, access to raw materials, etc.) and the economic feasibility of production. The technical capability alone does not make it possible to undertake production. The Decision recognizes this limitation and, in particular, the importance of economies of scale in its paragraph 6,³⁰ thereby suggesting that assessment of the existence of manufacturing capacity should not be limited to technical aspects.

A Member country may establish its lack of or insufficient manufacturing capacity and use the system to procure an active ingredient, even though it may have manufacturing capacity to formulate the corresponding product. Formulation is a less technically arduous process and occurs later in the production chain than manufacture of active ingredients.

It is important to note that the Decision does not determine particular criteria or methods to establish the lack of or insufficient capacity. This is a matter of self-assessment,³¹ the outcome of which cannot be challenged by another Member and cannot be subject to review, reversed or rejected by the Council for TRIPS. The Chair's Statement indicates that "[t]o promote transparency and avoid controversy, notifications under paragraph 2(a)(ii) of the Decision would include information on how the Member in question had established, in accordance with the Annex, that it has insufficient or no manufacturing capacities in the pharmaceutical sector". The Statement, however, does not amend the Decision. It

³⁰ "With a view to harnessing economies of scale for the purposes of enhancing purchasing power for, and facilitating the local production of, pharmaceutical products ...".

³¹ Vandoren, Van Eeckhaute, *op. cit.*, p. 785.

only suggests that Members' communicate information, for instance, about the type of analysis made, but not about the criteria or method employed, the data used, or the way in which conclusions were reached.³²

Confirming the intention to grant a compulsory licence

Finally, where a pharmaceutical product is patented in its territory, the importing country must notify the Council for TRIPS that it has granted or intends to grant a compulsory licence. It would be sufficient to notify the Council that the competent authority intends to grant a compulsory licence. There is no specified timeframe in which the compulsory licence must be issued after the notification is made.

The only condition imposed on the compulsory licence to be granted is that it be "in accordance with Article 31 of the TRIPS Agreement".³³ Hence, the importing country has to respect the conditions set out in this Article. It is not bound to apply more stringent conditions. In particular, there is no obligation to limit the compulsory licence to a limited quantity of the required product(s). The compulsory licence may be granted - as in any other situation - for the lifetime of the patent, subject only to the requirement of Article 31 (g) that the licence may be terminated under certain circumstances, "subject to adequate protection of the legitimate interests" of the compulsory licensee.

In addition, there is no obligation in the importing country to provide a compensation to the patent holder. The Decision waives application of Article 31 (h) and stipulates that compensation must be paid in the exporting country.

However, the Decision does not waive the application of Article 31 (b) of the TRIPS Agreement, despite the fact that countries willing to use the system would not be looking for a voluntary licence (unless some phases of production are locally made) but to purchase the final product. This can make the application of that provision a rather futile exercise.

³² The following types of notifications would indicate *how* the assessment was made:

"The Department/Ministry of ... has [reviewed information in its possession and] [, upon consultations with experts in the field of pharmaceuticals,] found that there is currently no capacity to manufacture [product(s)] in the country." or

"The Department/Ministry of ... has undertaken an enquiry among pharmaceutical producers established in [country] and determined that, excluding the patent owner's facilities, there is currently no capacity in the country to manufacture [product(s)] for the purposes of meeting its needs."

³³ A question may be raised as to whether this condition means that a compulsory licence may be granted to import pharmaceutical products under Article 31 even in cases where the national legislation does not provide for such grant or for the execution of the licence through importation. The adopted waiver means that a Member country will not have the right to complain against another Member not complying with Article 31 (f) or (h) but would not prevent, in principle, the patent owner from interfering with the granting of a compulsory licence if inconsistent with national law.

It is to be noted that, although paragraph 6 of the Doha Declaration and the Decision refer to “compulsory licences”, the system established by the Decision applies to any use without authorization of the right holder as contemplated in Article 31 of the TRIPS Agreement. This means that the importing country (as well as the exporting country) may apply the system on the basis of an authorization for *public non-commercial use*, and not necessarily under a compulsory licence granted to a third party. For such use without the authorization of the patent holder – often known as “government use” or “crown use” – the obligation for prior negotiation with the patent holder under Article 31 (b) is waived in all cases. In these cases, Members may also limit the remedies available to permit patent holders to seek compensation, without possibility of injunction (Article 44.2 of the TRIPS Agreement).

As mentioned before, notification of the grant of a compulsory licence, or the intention to grant a compulsory licence, is for informational purposes only. The importing country is not required to prove that the conditions provided for by Article 31 have been met, nor can the Council for TRIPS review or contest the content of the notification.³⁴

The notification will be made publicly available by the WTO Secretariat through a page on the WTO web site dedicated to the Decision. If the notification was made before the granting of the compulsory licence by the importing country, there is no need to make another notification after grant of the licence.

³⁴ However, the Statement by the Chair of the General Council indicates that:

- "In accordance with the normal practice of the TRIPS Council, notifications made under the system shall be brought to the attention of its next meeting.
- Any Member may bring any matter related to the interpretation or implementation of the Decision, including issues related to diversion, to the TRIPS Council for expeditious review, with a view to taking appropriate action.
- If any Member has concerns that the terms of the Decision have not been fully complied with, the Member may also utilize the good offices of the Director-General or Chair of the TRIPS Council, with a view to finding a mutually acceptable solution".

Compulsory licence in the exporting country

The Decision requires the exporting country to grant a compulsory licence.

The Decision does not waive the Article 31 (b) requirement that, prior to issuance of a compulsory licence, a request for a voluntary licence be made to the patent owner.³⁵

If the request for the voluntary licence is unsuccessful, the interested supplier would have to apply for a compulsory licence under the applicable national rules. The competent national authority would have to decide on the application and determine the remuneration to be paid. As mentioned above, this would require that the national law in the exporting country provide for the possibility of issuing a compulsory licence to satisfy a demand on the terms set out in the Decision.

The patent owner may appeal the government's decision to grant a compulsory licence. Depending on procedural rules in the exporting country, an appeal may not interfere with the immediate execution of the licence, or it may prevent the applicant from using the licence until the decision is confirmed. If the appeal does not suspend the execution of the licence, the applicant may start production and export but at the risk of a later claim for damages by the patent owner, if the decision to grant the compulsory licence were reversed.

The Decision sets out with some detail the conditions under which a compulsory licence can be issued by the exporting Member:

Amount necessary to meet needs

The compulsory licence must be granted only to produce and export "the amount necessary to meet the needs of the eligible importing Member(s)". In addition, the entirety of the production under licence shall be exported to the Member(s) which has notified its needs to the Council for TRIPS.

The "needs" are established by the importing country. The amount to be supplied is that actually agreed upon with the importing country (which autonomously determines what its needs are) and not necessarily what was indicated in the notification by the importing country (which only needs to specify the "expected" quantities, as previously mentioned). The "amount necessary to meet the needs" may be established on the basis of several criteria, depending on the degree to which the needs of the eligible importing country can be determined ex ante.

³⁵ As previously mentioned, it may be argued that the exporting country is entitled to consider the situation in the importing country as an emergency, or to recognize public non-commercial use, thus waiving the obligation for prior negotiations as required by Article 31 (b) of the TRIPS Agreement. This possibility would speed up the application of the system.

For instance, it may be based on a specified number of units of products when the needs can be precisely determined, or on the basis of patients to be treated or hospitals to be supplied over a period of time. In order to avoid the transaction costs and delays involved in obtaining a compulsory licence, it might also be possible to consider the granting of an amendable compulsory licence that expands the quantity to be supplied based on subsequent requests notified by the importing country(ies).

Given that one of the concerns underpinning the Decision is the risk of diversion, the criteria to determine quantities to be supplied should be established in good faith and be sufficient to determine the extent of use of the patented invention.

Identification of product(s)

(i) Labelling and marks

The Decision requires that the products to be supplied under the Decision be clearly identified "through specific labelling or marking". The purpose of the label or mark is to make the products identifiable in case there is diversion to other markets. This requirement may be satisfied by literally stating on the label that a product has been produced under the Decision,³⁶ but the requirement does not impose any specific indication. Hence, the supplier may choose what phrase or sign to utilize to make the products identifiable.

(ii) Packaging, colouring and shaping

Products should not only be identifiable but also distinguishable, presumably from the branded products. This is to be achieved, according to the Decision, through special packaging and/or the colouring/shaping of the products themselves.

Despite the apparent ambiguity of the expression "colouring/shaping", it is clear that these requirements are not cumulative.³⁷ It will be up to the supplier to choose whether to distinguish through packaging, colouring or shaping.

The differences in packaging, colouring or shaping should be those reasonably necessary to enable the distinction to be made. The Decision does not state, however, who should be able to distinguish the products. The requirements may be differently implemented depending on whether the products are to be distinguishable to customs authorities, distributors and retailers, medical doctors, or the general public. Since the objective of this provision is not to protect consumers but to protect pharmaceutical companies against diversion,³⁸

³⁶ For instance, by indicating in the label "Product made for country X under the WTO General Council Decision of 30 August 2003 (WT/L/540)".

³⁷ See the second paragraph of the Statement by the Chair of the General Council where reference is explicitly made to "packaging ... colouring *or* shaping" (emphasis added).

³⁸ See the second paragraph of the Statement by the Chair of the General Council which indicates that "Members recognize that the purpose of the Decision would be defeated if products supplied under this Decision are diverted from the markets for which they are intended. Therefore, all reasonable measures should be taken to prevent such diversion in accordance with the relevant paragraphs of the Decision".

the differences should be those sufficient for customs authorities or pharmaceutical manufacturers (in the case of active ingredients) to distinguish the products. In addition, it is to be noted that while special packaging is not likely to impose a heavy burden on suppliers, changes in colour or shape may require new bioequivalence and bioavailability studies (if such studies had already been made before) thereby delaying the supply of the products and increasing their prices.

The Decision seems to refer to differentiation of finished products only. However, the Statement indicates that "the provisions of paragraph 2(b)(ii) apply not only to formulated pharmaceuticals produced and supplied under the system but also to active ingredients produced and supplied under the system and to finished products produced using such active ingredients". Whatever the legal value of the Statement (an issue not addressed in this document), the differentiation of an active ingredient by shape may be impossible (since it would normally be provided in powder, liquid or other amorphous form), while differentiation by colour would require inclusion of unnecessary additives and would change the chemical composition of the product. Packaging would seem the only reasonable option for differentiation of active ingredients. Since they are traded between specialized companies, however, differentiation of active ingredients, as opposed to finished products, may not be necessary to prevent diversion.

The obligation to distinguish the products is not absolute. Exporters do not need to distinguish the products when doing so (i) is not feasible, or (ii) will have a significant impact on price.

There are no parameters in the Decision to determine what constitutes a "significant impact on price". Since the Decision's aim is to address the public health needs of Member countries – in the framework of the overall objective of the Doha Declaration to ensure access to medicines for all (paragraph 4) – the significance of the increase in price should be assessed from the perspective of the purchaser. Any increase in price may be "significant" for the purchaser and limit its capacity to address public health needs, particularly in the case of expensive products or purchases in big volumes.

Nor does the Decision specify who should assess whether the impact is significant. It is apparently the supplier who is expected to make this judgment, which should be made taking the purchasers' interests into account.

The Statement indicates that "[i]t is the understanding of Members that in general special packaging and/or special colouring or shaping should not have a significant impact on the price of pharmaceuticals". This ambiguous statement may be read as a recognition that special packaging, colouring or shaping generally does not have a significant impact, or as a normative statement emphasizing the idea that the use of such distinction should not have such a negative impact. This second reading corresponds to the literal wording of the text. Though it may be seen as redundant, it does clarify that colouring and shaping are alternative and not cumulative, and expresses the Members' concern that the distinction of products must not significantly increase prices.

It is important to note that obtaining a compulsory licence may not be sufficient for a company to be able to export a pharmaceutical product under the system, as national health regulations generally require prior approval from national drug regulatory agencies for the production of medicines for export.

Notification by the supplier

Under the terms of the compulsory licence granted in the supplying country, the supplier should post on a web site certain information before shipment begins. The licensee may use its own web site or the page on the WTO web site dedicated to the Decision. The information must include (i) the quantities being supplied to each destination, and (ii) the distinguishing features of the product(s).

The obligation to provide information is limited to the "distinguishing features", and does not encompass other information about the product. It may include, for instance, an image showing the product as packaged or its label, or indication of its colour or shape, depending on the distinguishing characteristic chosen by the supplier.

Notification by the exporting country

In addition to the supplier's notification, the exporting country must notify the Council for TRIPS of the grant of the licence. As in the case of the notification by the importing country, this notification does not need to be approved by any WTO body (footnote 8 of the Decision). The Council for TRIPS has no authority to review the notification nor to object to the grounds and conditions under which the compulsory licence has been granted. Nor can it observe deficiencies in the notification either (for instance, if some of the required information was missing).³⁹ The notification will be made available publicly by the WTO Secretariat through a page on the WTO web site dedicated to the Decision.

The notification must contain the following:

- the name and address of the licensee;
- the product(s) for which the licence has been granted;
- the quantity(ies) for which it has been granted;
- the country(ies) to which the product(s) is (are) to be supplied;
- the duration of the licence;
- the address of the web site where the supplier will post the information referred to in paragraph 2 (b)(iii) of the Decision.

³⁹ The Statement by the Chair of the General Council, however, indicates that "[a]ny Member may bring any matter related to the interpretation or implementation of the Decision, including issues related to diversion, to the TRIPS Council for expeditious review, with a view to taking appropriate action." In addition, "if any Member has concerns that the terms of the Decision have not been fully complied with, the Member may also utilize the good offices of the Director-General or Chair of the TRIPS Council, with a view to finding a mutually acceptable solution".

The specified content of the notification suggests that, although a compulsory licence is to be granted for a limited quantity only, a single compulsory licence may cover the production for and export to more than one country. Several importing countries may, in fact, pool their purchasing power for a set of pharmaceutical products, in order to obtain better prices. The Decision also allows a country member of a regional trade agreement, at least half of which is made up of LDCs, to re-export products acquired under the system established by the Decision to other developing or LDC parties to the regional trade agreement that "share the health problem in question" (paragraph 6(i)). The main advantage created by this provision is that the waiver of Article 31 (f) applies to all members of the trade agreement and there is no need to notify the Council for TRIPS each time that an exportation is made. However, this exception only applies to some regional trade agreements in Africa, and not to the bigger regional markets in Asia and Latin America, where more significant economies of scale could be attained. Moreover, the Decision does not allow the supplier to supply all or some of the eligible members of the regional trade agreement. The exception applies only to permit an importing trade agreement member to re-export to others.

The duration of the compulsory licence is to be determined by the exporting country's government. It would be logical to provide for its termination upon the effective supply of the required quantities of a given product, in order to avoid the burden and cost of requiring repeated compulsory licences if delivery takes place over a period of time.

Anti-diversion measures

According to paragraph 4 of the Decision, "in order to ensure that the products imported under the system set out in this Decision are used for the public health purposes underlying their importation, eligible importing Members shall take reasonable measures within their means, proportionate to their administrative capacities and to the risk of trade diversion to prevent re-exportation of the products that have actually been imported into their territories under the system. In the event that an eligible importing Member that is a developing country Member or a least-developed country Member experiences difficulty in implementing this provision, developed country Members shall provide, on request and on mutually agreed terms and conditions, technical and financial cooperation in order to facilitate its implementation".

The Statement emphasizes that "the purpose of the Decision would be defeated if products supplied under this Decision are diverted from the markets for which they are intended" and indicates that "all reasonable measures should be taken to prevent such diversion in accordance with the relevant paragraphs of the Decision". Though the wording here appears somehow stronger than in the Decision, it neither alters the content nor the nature of the best efforts obligation imposed by the latter. It will be the prerogative of the importing country to determine what is:

- reasonable within the Member's means
- proportionate to its administrative capacities
- proportionate to the risk of trade diversion.

General measures on pharmaceuticals need not be adopted, but only those necessary in relation to "products that have actually been imported into their territories under the system".

Suspension of the system

The second alternative in the Annex to the Decision indicates that "When it is established that such [manufacturing] capacity has become sufficient to meet the Member's needs, the system shall no longer apply". This condition applies only when a country has determined that it has insufficient manufacturing capacity; it does not apply when the determination was that the country lacks manufacturing capacity altogether.

This Decision does not mention who is to make the determination that the capacity has become sufficient nor the applicable procedures. Since it is the importing country itself which determines insufficient capacity, and the Council for TRIPS has no power to review this determination, it is logical to interpret that the importing country should also make the determination that capacity has become sufficient. Given that lack or insufficient capacity is to be established per product, and that compulsory licences are issued to import a specified quantity of a needed pharmaceutical product(s), the determination that capacity has become sufficient would not affect the future use of the system with regard to other product(s).

Conclusions

The WTO General Council Decision allows Member countries to grant compulsory licences for the export of pharmaceutical products without the restriction established by Article 31 (f) of the TRIPS Agreement, and permits the importing country not to provide compensation to the patent owner where a compulsory licence is granted. The Decision may be also applied on the basis of government non-commercial use, an avenue that in many instances may be quicker, simpler and more effective than the granting of a compulsory licence.

In addition to the steps and procedures stipulated by the Decision, legislative changes are likely to be necessary in both the exporting and importing countries in order to implement the Decision. The conditions under which a compulsory licence can be obtained will influence the speed and cost of making the system operative. Recourse to non-commercial government use may be the most appropriate way in many cases, as the requirement of Article 31 (b) may be waived. A summary of some of the issues to be considered and the steps to be taken to make the system operational are included in Annex 2.

Finally, countries willing to use the Decision should ensure that legal obstacles are not erected through data exclusivity obligations, the “linkage” between product patents and drug registration, or through other regulations.

Annex 1

WORLD TRADE ORGANIZATION

WT/L/540
2 September 2003

(03-4582)

IMPLEMENTATION OF PARAGRAPH 6 OF THE DOHA DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH

Decision of 30 August 2003*

The General Council,

Having regard to paragraphs 1, 3 and 4 of Article IX of the Marrakesh Agreement Establishing the World Trade Organization ("the WTO Agreement");

Conducting the functions of the Ministerial Conference in the interval between meetings pursuant to paragraph 2 of Article IV of the WTO Agreement;

Noting the Declaration on the TRIPS Agreement and Public Health (WT/MIN(01)/DEC/2) (the "Declaration") and, in particular, the instruction of the Ministerial Conference to the Council for TRIPS contained in paragraph 6 of the Declaration to find an expeditious solution to the problem of the difficulties that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face in making effective use of compulsory licensing under the TRIPS Agreement and to report to the General Council before the end of 2002;

Recognizing, where eligible importing Members seek to obtain supplies under the system set out in this Decision, the importance of a rapid response to those needs consistent with the provisions of this Decision;

Noting that, in the light of the foregoing, exceptional circumstances exist justifying waivers from the obligations set out in paragraphs (f) and (h) of Article 31 of the TRIPS Agreement with respect to pharmaceutical products;

* This Decision was adopted by the General Council in the light of a statement read out by the Chairman, which can be found in JOB(03)/177. This statement will be reproduced in the minutes of the General Council to be issued as WT/GC/M/82.

Decides as follows:

1. For the purposes of this Decision:
 - (a) "pharmaceutical product" means any patented product, or product manufactured through a patented process, of the pharmaceutical sector needed to address the public health problems as recognized in paragraph 1 of the Declaration. It is understood that active ingredients necessary for its manufacture and diagnostic kits needed for its use would be included¹;
 - (b) "eligible importing Member" means any least-developed country Member, and any other Member that has made a notification² to the Council for TRIPS of its intention to use the system as an importer, it being understood that a Member may notify at any time that it will use the system in whole or in a limited way, for example only in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. It is noted that some Members will not use the system set out in this Decision as importing Members³ and that some other Members have stated that, if they use the system, it would be in no more than situations of national emergency or other circumstances of extreme urgency;
 - (c) "exporting Member" means a Member using the system set out in this Decision to produce pharmaceutical products for, and export them to, an eligible importing Member.
2. The obligations of an exporting Member under Article 31(f) of the TRIPS Agreement shall be waived with respect to the grant by it of a compulsory licence to the extent necessary for the purposes of production of a pharmaceutical product(s) and its export to an eligible importing Member(s) in accordance with the terms set out below in this paragraph:
 - (a) the eligible importing Member(s)⁴ has made a notification² to the Council for TRIPS, that:
 - (i) specifies the names and expected quantities of the product(s) needed⁵;
 - (ii) confirms that the eligible importing Member in question, other than a least-developed country Member, has established that it has insufficient or no manufacturing capacities in the pharmaceutical sector for the product(s) in question in one of the ways set out in the Annex to this Decision; and

¹ This subparagraph is without prejudice to subparagraph 1(b).

² It is understood that this notification does not need to be approved by a WTO body in order to use the system set out in this Decision.

³ Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Japan, Luxembourg, the Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland, the United Kingdom and the United States.

⁴ Joint notifications providing the information required under this subparagraph may be made by the regional organizations referred to in paragraph 6 of this Decision on behalf of eligible importing Members using the system that are parties to them, with the agreement of those parties.

⁵ The notification will be made available publicly by the WTO Secretariat through a page on the WTO website dedicated to this Decision.

- (iii) confirms that, where a pharmaceutical product is patented in its territory, it has granted or intends to grant a compulsory licence in accordance with Article 31 of the TRIPS Agreement and the provisions of this Decision⁶;
- (b) the compulsory licence issued by the exporting Member under this Decision shall contain the following conditions:
- (i) only the amount necessary to meet the needs of the eligible importing Member(s) may be manufactured under the licence and the entirety of this production shall be exported to the Member(s) which has notified its needs to the Council for TRIPS;
 - (ii) products produced under the licence shall be clearly identified as being produced under the system set out in this Decision through specific labelling or marking. Suppliers should distinguish such products through special packaging and/or special colouring/shaping of the products themselves, provided that such distinction is feasible and does not have a significant impact on price; and
 - (iii) before shipment begins, the licensee shall post on a website⁷ the following information:
 - the quantities being supplied to each destination as referred to in indent (i) above; and
 - the distinguishing features of the product(s) referred to in indent (ii) above;
- (c) the exporting Member shall notify⁸ the Council for TRIPS of the grant of the licence, including the conditions attached to it.⁹ The information provided shall include the name and address of the licensee, the product(s) for which the licence has been granted, the quantity(ies) for which it has been granted, the country(ies) to which the product(s) is (are) to be supplied and the duration of the licence. The notification shall also indicate the address of the website referred to in subparagraph (b)(iii) above.

3. Where a compulsory licence is granted by an exporting Member under the system set out in this Decision, adequate remuneration pursuant to Article 31(h) of the TRIPS Agreement shall be paid in that Member taking into account the economic value to the importing Member of the use that has been authorized in the exporting Member. Where a compulsory licence is granted for the same products in the eligible importing Member, the obligation of that Member under Article 31(h) shall be waived in respect of those products for which remuneration in accordance with the first sentence of this paragraph is paid in the exporting Member.

⁶ This subparagraph is without prejudice to Article 66.1 of the TRIPS Agreement.

⁷ The licensee may use for this purpose its own website or, with the assistance of the WTO Secretariat, the page on the WTO website dedicated to this Decision.

⁸ It is understood that this notification does not need to be approved by a WTO body in order to use the system set out in this Decision.

⁹ The notification will be made available publicly by the WTO Secretariat through a page on the WTO website dedicated to this Decision.

4. In order to ensure that the products imported under the system set out in this Decision are used for the public health purposes underlying their importation, eligible importing Members shall take reasonable measures within their means, proportionate to their administrative capacities and to the risk of trade diversion to prevent re-exportation of the products that have actually been imported into their territories under the system. In the event that an eligible importing Member that is a developing country Member or a least-developed country Member experiences difficulty in implementing this provision, developed country Members shall provide, on request and on mutually agreed terms and conditions, technical and financial cooperation in order to facilitate its implementation.

5. Members shall ensure the availability of effective legal means to prevent the importation into, and sale in, their territories of products produced under the system set out in this Decision and diverted to their markets inconsistently with its provisions, using the means already required to be available under the TRIPS Agreement. If any Member considers that such measures are proving insufficient for this purpose, the matter may be reviewed in the Council for TRIPS at the request of that Member.

6. With a view to harnessing economies of scale for the purposes of enhancing purchasing power for, and facilitating the local production of, pharmaceutical products:

- (i) where a developing or least-developed country WTO Member is a party to a regional trade agreement within the meaning of Article XXIV of the GATT 1994 and the Decision of 28 November 1979 on Differential and More Favourable Treatment Reciprocity and Fuller Participation of Developing Countries (L/4903), at least half of the current membership of which is made up of countries presently on the United Nations list of least-developed countries, the obligation of that Member under Article 31(f) of the TRIPS Agreement shall be waived to the extent necessary to enable a pharmaceutical product produced or imported under a compulsory licence in that Member to be exported to the markets of those other developing or least-developed country parties to the regional trade agreement that share the health problem in question. It is understood that this will not prejudice the territorial nature of the patent rights in question;
- (ii) it is recognized that the development of systems providing for the grant of regional patents to be applicable in the above Members should be promoted. To this end, developed country Members undertake to provide technical cooperation in accordance with Article 67 of the TRIPS Agreement, including in conjunction with other relevant intergovernmental organizations.

7. Members recognize 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 Declaration. To this end, eligible importing Members and exporting Members are encouraged to use the system set out in this Decision in a way which would promote this objective. Members undertake to cooperate in paying special attention to the transfer of technology and capacity building in the pharmaceutical sector in the work to be undertaken pursuant to Article 66.2 of the TRIPS Agreement, paragraph 7 of the Declaration and any other relevant work of the Council for TRIPS.

8. The Council for TRIPS shall review annually the functioning of the system set out in this Decision with a view to ensuring its effective operation and shall annually report on its operation to the General Council. This review shall be deemed to fulfil the review requirements of Article IX:4 of the WTO Agreement.

9. This Decision is without prejudice to the rights, obligations and flexibilities that Members have under the provisions of the TRIPS Agreement other than paragraphs (f) and (h) of Article 31, including those reaffirmed by the Declaration, and to their interpretation. It is also without prejudice to the extent to which pharmaceutical products produced under a compulsory licence can be exported under the present provisions of Article 31(f) of the TRIPS Agreement.

10. Members shall not challenge any measures taken in conformity with the provisions of the waivers contained in this Decision under subparagraphs 1(b) and 1(c) of Article XXIII of GATT 1994.

11. This Decision, including the waivers granted in it, shall terminate for each Member on the date on which an amendment to the TRIPS Agreement replacing its provisions takes effect for that Member. The TRIPS Council shall initiate by the end of 2003 work on the preparation of such an amendment with a view to its adoption within six months, on the understanding that the amendment will be based, where appropriate, on this Decision and on the further understanding that it will not be part of the negotiations referred to in paragraph 45 of the Doha Ministerial Declaration (WT/MIN(01)/DEC/1).

ANNEX

Assessment of Manufacturing Capacities in the Pharmaceutical Sector

Least-developed country Members are deemed to have insufficient or no manufacturing capacities in the pharmaceutical sector.

For other eligible importing Members insufficient or no manufacturing capacities for the product(s) in question may be established in either of the following ways:

- (i) the Member in question has established that it has no manufacturing capacity in the pharmaceutical sector;

OR

- (ii) where the Member has some manufacturing capacity in this sector, it has examined this capacity and found that, excluding any capacity owned or controlled by the patent owner, it is currently insufficient for the purposes of meeting its needs. When it is established that such capacity has become sufficient to meet the Member's needs, the system shall no longer apply.

Annex 2: Summary of context and steps required to use the system

Issues to be considered

- There is no need to follow the Decision procedures if there is an agreement by the patent owner or his voluntary licensee to supply the required pharmaceutical product(s) at prices agreeable to the importing country. The need to use the Decision arise if the patent owner refuses to supply on mutually agreed conditions.
- If an agreement with the patent owner is not reached, the prospective importing country should determine which patents are relevant in the importing and exporting country and their legal status. This may not be a simple task since, as previously mentioned, several patents usually protect, directly or indirectly, a product. Moreover, patents expire after the specified period of duration and for lack of payment of maintenance fees. Before taking action, the existence of enforceable patents should be confirmed. An option that governments may follow when Article 31 (b) is not applicable (e.g. in cases of emergency), is to grant a compulsory licence covering all patents (whether identified or not) relating to a product (including processes and, if relevant, indications) that would be infringed in case of importation.¹
- The possibility of using the Decision will depend on certain aspects of the national patent laws in the importing and exporting countries. The law in the importing country must provide for compulsory licences under which imports can be made to address public health needs, and the law in the exporting country must allow for exports in cases (not covered by Article 31 (k) of the TRIPS Agreement) where export markets are predominantly supplied. The national law in the importing country should also permit the implementation of the waiver of Article 31 (h) regarding compensation to the patent owner when products are being imported pursuant to the Decision.
- A dissatisfied patent owner may use the legal mechanisms available under the laws of the importing and/or exporting country to challenge the compulsory licence, the compensation to be paid (in the exporting country) or other aspects of the transactions made under the Decision.

¹ See, e.g. the notice of authorization for the exploitation of patented inventions issued by the Government of Malaysia on 29 October 2003 relating to didanosine, zidovudine and lamivudine, and the compulsory licence granted by the Government of Mozambique (No. 01/MIC/04) in May 2004.

Context

Access to needed product refused	Refusal of the patent owner to supply drugs at a price acceptable to importing country
Patent status in the importing and exporting country	Identification and analysis of relevant patents and of their validity
Compulsory licence (CL) to import allowed by national law in importing country	Law in the importing country allows for the granting of CL to import in order to satisfy public health needs; in cases of emergency, for public interest, to remedy anti-competitive practices, for non-commercial government use or on other grounds
Implementation of waiver on compensation (Article 31 (h) of the TRIPS Agreement)	Law in the importing country has been adapted to use the waiver relating to the compensation to the patent owner
CL for export allowed by national law in exporting country	Exporting country's law has been amended, as necessary, to implement waiver of Article 31 (f) of the TRIPS Agreement

Steps in the importing Member country

The steps for the importing country to use the Decision are summarized in the following table. As previously mentioned, differences exist in some aspects of the procedures depending on whether the importing country is a LDC or a developing country not falling within this category. The steps indicated below are not necessarily sequential (for instance, the notification of the importing country can be made before or after the granting of a compulsory licence).

Steps to use Decision	LDCs	Other Members
Notification of intention to use the system	Not required	Notification with or without limitations
Establishing lack of or insufficient manufacturing capacity	Not required	Required
Notification of product's name and quantities, intention to grant or granting of CL and lack of or insufficient manufacturing capacity	Notification of lack of or insufficient manufacturing capacity not required	Required

Steps to use Decision	LDCs	Other Members
Preliminary procedures to obtain a CL if relevant patents are in force in the importing country	Unless the prior request of a voluntary licence does not apply, an entity in the importing country must seek a voluntary licence from the patent owner	Unless the prior request of a voluntary licence does not apply, an entity in the importing country must seek a voluntary licence from the patent owner
Application for and processing of CL request	Compliance with national laws	Compliance with national laws
Granting of CL in importing country, before or after the notification	CL may be for unlimited quantity, as long the patent is in force, and without compensation	CL may be for unlimited quantity, as long the patent is in force, and without compensation
Review of CL	The granting of a CL may be challenged by the patent owner and subject to review by a higher authority. Depending on national law, the review need not suspend the execution of the licence	The granting of a CL may be challenged by the patent owner and subject to review by a higher authority. Depending on national law, the review need not suspend the execution of the licence
Registration of products with health authority in the importing country	<p>Proof of bioequivalence and bioavailability, if required by national law</p> <p>If, in the importing country, data exclusivity is granted with regard to data submitted for the registration of medicines, the data holder's authorization would be required, unless the use of such data is included² in the CL³</p>	<p>Proof of bioequivalence and bioavailability, if required by national law</p> <p>If, in the importing country, data exclusivity is granted with regard to data submitted for the registration of medicines, the data holder's authorization would be required, unless the use of such data is included in the CL</p>

² There are precedents of this kind in the USA. See Correa, C (1999), *Intellectual property rights and the use of compulsory licenses: options for developing countries*, Trade-Related Agenda, Development and Equity, Working Paper No. 5, Geneva, South Centre, 1999, p.16.

³ Provisions allowing the use of data in cases of the granting of a compulsory licence may need to be incorporated into national laws, in order to prevent legal challenges that could otherwise block the exploitation of the licence.

Steps to use Decision	LDCs	Other Members
Anti-diversion measures in the importing country	Adoption of reasonable measures within their means, proportionate to their administrative capacities and to the risk of trade diversion to prevent re-exportation of the products that have actually been imported into their territories under the system	Adoption of reasonable measures within their means, proportionate to their administrative capacities and to the risk of trade diversion to prevent re-exportation of the products that have actually been imported into their territories under the system

Steps in the exporting Member country

In addition to a possible legislative change, a number of actions need to be taken by the prospective supplier and exporting country in order to apply the Decision.

Steps to use Decision	Actions required
Preliminary procedures to obtain a CL	Unless the prior request of a voluntary licence does not apply, an entity in the exporting country must seek a voluntary licence from the patent owner
Application for a CL	<ul style="list-style-type: none"> • Only for a limited amount • Entirety of production for export
Granting of CL including determination of compensation to patent owner	Compliance with national laws
Review of CL	The granting of a CL may be challenged by the patent owner and subject to review by a higher authority. The review need not suspend the execution of the licence
Notification by exporting country	Information about the conditions attached to the CL, including the name and address of the licensee, the product(s) for which the licence has been granted, the quantity(ies) for which it has been granted, the country(ies) to which the product(s) is (are) to be supplied, the duration of the licence and the address of the web site where the supplier will post information about shipment

Steps to use Decision	Actions required
Production and product differentiation	Develop the chemistry and formulate the drug (when produced by the licensee for the first time), and investigate the shape, colouring, labelling and packaging of the patent-holder's product in the importing country in order to differentiate the product for export
Notification by the supplier before shipment	Information about quantities and distinguishing features of products