in country A, or if they are available, but they were produced and sold by a licensee under a compulsory license, country B will not be able to import those, or it will be able to import those products in small quantities only, in accordance with the provisions of Article 3 1(f) of the TRIPS Agreement; in this case, a compulsory license for exportation purposes must be granted in country A, under this Decision.

c) Patents have been granted in both countries A and B for the same pharmaceutical products and are held by the same patent owner or by someone under the control of the owner of the patent granted in country A. In that event, and if the products are available in A in reasonable quantities, quality and price, their importation into country B may be free under an international exhaustion regime. But if they are not available in A, or if they are, but at unreasonable prices or in insufficient quantities, a compulsory license for exportation purposes must be obtained in country A. And because patent rights are not exhausted if the products are sold under a compulsory license, a second compulsory license for importation purposes is needed in country B. According to the Decision, the remuneration is to be paid only once, in country A (the exporting country), but taking into account the economic value of the use in country B (the importing country).

d) Patents have been granted in both countries A and B for the same pharmaceutical products and are held by different patent owners that have no reciprocal interest in the respective social capitals. The solution given by the Decision and explained in indent c) applies, except that the patent owner in country B may also have a legitimate right to receive an adequate compensation for the use. Any different solution, absent any fraudulent intent, would lead the patent rights in country B to be confiscated. This situation, however, is not covered by the Decision, but it is possibly covered by national legislation on the protection of private property rights.

[16] - As said above, the operation of the Decision could include the transfer of technology to the importing WTO Member (even though that aspect is not mandatory). Actually, countries without manufacturing capacity or with insufficient capacity may wish to use the mechanism established by the Decision to build partnerships with generic exporters in other countries.

[17] - This provision is necessary for those developing countries that have informed the Secretariat of the WTO that they would only use the system as importers in situations of national emergencies or other circumstances of extreme urgency.

[18] - Even though paragraph 2(b) of the Decision, which contains the conditions of the non-voluntary license, refers to the exporting Member only, those conditions, *mutatis mutandis*, also apply to the non-voluntary license in the importing country, if any. This results from the language of paragraph 2(a)(iii) of the Decision, which says that, if a non-voluntary license has to be granted in the importing country, it must comply with Article 31 of the TRIPS Agreement and the provisions of the Decision.

[19] - This provision mirrors a similar (and reciprocal) provision contained in Section 13A(I)(4)(a) *supra*. According to the language of paragraph 6(i) of the Decision, the waiver that benefits those regional trade agreements that qualify under that provision applies not only to the exportation of produced pharmaceutical products to destinations other than those initially identified in the licensing agreement (but provided that those other destinations are within the same customs territory), but also to the re-exportation of imported products

(provided that the destination of the re-exported products is within the same customs territory). It is important to note that this extension of the waiver does not apply to regional intellectual property organizations, because, as such, they do not have a trade-related nature. However, those Members of a regional IP organization that are also parties to a regional trade agreement that qualifies under paragraph 6(i) of the Decision are eligible as importers (or exporters) for the extended waiver, but rather in the capacity of parties to that regional trade agreement. It should be noted that if there is more than one importing country and the imported product is patented in all or some of them, each country where a patent is in force must grant a compulsory license. This is due to the territorial effects of patents. Nevertheless, in such an event, the provisions of section 13A(I)(5) — which reflect the waiver as regards Article 31(h) of the TRIPS Agreement — would apply.

[20] - The waiver of Article 31(f) of the TRIPS Agreement is subject to the condition that the importer is importing with the aim of supplying the local market. Absent the conditions set out by paragraph 6(i) of the Decision (see comment [19] above), the importer may not re-export the imported products.

[22] - The information about the economic value of the use of the invention in the importing country is of crucial importance for determining the adequate remuneration to be paid to the patent owner in the exporting country. That information is naturally in control of the importer — which can be a private company, or a government agency, or an intergovernmental organization, or a non-governmental organization — and therefore it must be communicated to the authority in the exporting country who is in charge of determining the remuneration to be paid. However, the suggested language has been placed between square brackets because neither the TRIPS Agreement nor the Decision defines "economic value" and, ultimately, that is a matter for the exporting Member to consider. Therefore, the importing Member may prefer not to legislate in detail on this particular issue.

[23] - Section 13(A)(II)(7) deals with another aspect left unattended by the Decision: the issue of avoiding unfair commercial use of test data where the importing country subjects pharmaceutical products to marketing approval. This problem does not arise in principle in the exporting country, because the licensed products are not destined to be consumed in the territory of the granting country, but rather in the territory of another (requesting) eligible importing WTO Member. However, the issue arises in the importing country. The solution is that the reliance by the government on test data for registering the pharmaceutical product is a natural component of the economic value of its use and thus it is already comprised in the amount of the adequate remuneration paid in the exporting country (or, in the event the patent owner in the importing country is a different entity, as explained above, in note 21, in the remuneration paid to that patent owner in the importing country). Nonetheless, the importing Member is still obliged to protect the undisclosed information against disclosure. There is, however, a remote possibility that the pharmaceutical product covered by a patent in the exporting country is not covered by a parallel patent in the importing country and yet a local pharmaceutical company has submitted test data on a new chemical element used by that product in order to obtain marketing approval in the importing country. In that event, the sanitary authorities may need to compulsorily rely on those test data in order to approve the marketing of the imported products, provided an adequate compensation be paid to the first registrant and if its term of protection has not yet expired. This situation has not been covered by the Decision and thus, it is not reflected in the proposed provisions.

[24] - As noted above, the Decision may apply even where a patent has not been granted in the importing country, because the main problem to face by countries without (or with insufficient) local capacity to manufacture pharmaceutical products was the prohibition of manufacturing products under a compulsory license mainly or exclusively for exportation purposes. Therefore, where a patent has not been granted in the importing country, some provisions must be adapted, namely those that imply or are based on the grant of a patent in the importing country.

Draft provisions for a least-developed country Member of the WTO[1)]

(I) As an exporter[2)]

1. Where a pharmaceutical product is covered by a patent and the Minister receives a request by the competent authority of another WTO Member to authorize the production of that product and its exportation into the territory of that other WTO Member, the Minister may so authorize provided the following conditions are met:

(a) the requesting WTO Member is an eligible importing Member; and

(b) the Minister is satisfied that the requesting eligible importing Member has made a notification to the Council for TRIPS, that:

(i) specifies the names and expected quantities of the product(s) needed; and

(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; and

(iii) confirms that, where a pharmaceutical product is patented in its territory, it has granted or intends to grant a compulsory license in accordance with Article 31 of the TRIPS Agreement and the provisions of the Decision of the General Council of August 30, 2003, on the Implementation of the Doha Decision on the TRIPS Agreement and Public Health ("the Decision").

2. The non-voluntary license or authorization granted by the Minister shall contain the following conditions:

(a) 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 requesting Member;
(b) products produced under the licence shall be bear on their label and/or package, in clearly legible characters, the following notice: "products manufactured and sold under the system set out in the Decision of the WTO General Council of August 30, 2003, on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health;"
(c) the licensee shall 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 the price; and
(d) before shipment begins, the licensee shall post on its website or a WTO website the following information:

- the quantities being supplied to each destination as referred to in subparagraph (a) above; and

- the distinguishing features of the product(s) referred to in subparagraph (c) above.

[(e) the obligation for the licensee to transfer to an entity in the eligible importing WTO Member to be designated by the Ministry of Health of the eligible importing WTO Member the necessary technology for manufacturing the patented product, including methods for monitoring and maintaining effective quality controls.]

3. The Minister shall notify the Council for TRIPS of the grant of the license, including the conditions attached to it, without undue delay. The information provided shall include the name and address of the licensee, the product(s) for which the license 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 license. The notification shall also indicate the address of the website referred to in subparagraph (2)(d) above.

4. The licensee shall be responsible for taking reasonable measures to avoid trade diversion and exportation of the products produced under the non-voluntary license to destinations other than that (or those) specified in the non-voluntary license. Any act that constitutes trade diversion leading to exportation of the products produced under the non-voluntary license to other destinations shall be deemed an infringement of the patent, and subject to civil, administrative and criminal sanctions applicable. In addition, that license may be cancelled. The Minister, in that event, may grant a license to another person under the same or similar conditions.

[(a)If [the country] is 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 patented pharmaceutical products covered by the non-voluntary license may be exported to any other party to the same regional trade agreement that share the health problem in question.]

5. All the conditions established in Sections 12 and 13 shall apply *mutatis mutandis* to compulsory licenses granted under this Section, except for Section 12(7), which shall not apply, and Section 12(2), concerning the payment of adequate remuneration to the patent owner, pursuant to Article 31(h) of the TRIPS Agreement, and which shall be paid taking into account the economic value to the importing Member of the use that has been authorized by the Minister.

6. For the purposes of this Section,

(a) "pharmaceutical product" means any patented product, or product manufactured through a patented process, of the pharmaceutical sector needed to address public health problems afflicting the importing country or territory;

(b) "eligible importing WTO Member" means a least-developed country WTO Member, or a developing country that has previously made a notification to the Council of TRIPS of the WTO to import pharmaceutical products under the system established by the Decision ("the system").

(II)As an importer

1. Where a pharmaceutical product is covered by a patent the Minister may authorize its importation from another WTO Member under the system, provided that the Minister has previously made a notification to the Council for TRIPS, that:

(a) specifies the names and expected quantities of the product(s) needed; and
(b) confirms that it has granted or intends to grant a compulsory license in accordance with Article 31 of the TRIPS Agreement and the provisions of the Decision of the General Council of August 30, 2003, on the Implementation of the Doha Decision on the TRIPS Agreement and Public Health;

(c) confirms the name of the entity that has been identified as receiver of the technology for the purposes of Section 13A(I)(2)(e) above.

2. Only the amount necessary to meet the needs of [the country] may be imported under the system.

3. The Minister shall notify the Council for TRIPS of the grant of the license, including the conditions attached to it, without undue delay.

4. The licensee shall be responsible for taking reasonable measures to avoid trade diversion and re-exportation of the products imported under the non-voluntary license. Any act that constitutes trade diversion leading to re-exportation of the products imported under the non-voluntary license shall be deemed an infringement of the patent, and subject to civil, administrative and criminal sanctions applicable. In addition, if a non-voluntary license of a patent has been granted in [the country] for the purposes of importing pharmaceutical products produced and exported under a non-voluntary license, that license may be cancelled. The Minister, in that event, may grant a license to another person under the same or similar conditions.

[(a)Re-exportation of imported pharmaceutical products is permitted if [the country] and the importing WTO Members are parties to the same regional trade agreements 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. If such re-exportation occurs, it will be reflected in the economic value of the use for the purposes of paragraph 5, *infra*, but there will be no need for a new compulsory license to be granted.]

5. All the conditions established in Sections 12 and 13 shall apply *mutatis mutandis* to compulsory licenses granted under this Section, except for the provisions contained in Section 12(7), whereby the importation shall be exclusively for the supply of the local market, and Section 12(2), which shall not apply if the patent owner in the exporting country WTO Member is the same entity or a different entity under the control of the same entity that owns the patent on the same pharmaceutical product in [the country]. In the event the owner of the patented granted in [the country] is not the same entity or is not under the control of the same entity that owns the patent for the same pharmaceutical

products in question in the exporting country, the patent owner shall be entitled to perceive adequate remuneration pursuant to Article 31(h) of the TRIPS Agreement taking into account the value of the use in [the country].

6. The importer shall inform the non-voluntary license granting authority as well as the patent owner and the licensee in the exporting WTO Member, about the economic value of the use of the patented invention in [the country].

[(a) The information shall include all data that may be deemed relevant for assessing the economic value in [the country], but it shall include at least data concerning the following:

(i) the quantities of imported pharmaceutical products distributed and effectively delivered to patients, doctors, health institutes, such as hospitals, clinics and medical outposts, or government agencies, and any other entity in charge of delivering health care;

(ii) the price at which the pharmaceutical products will be sold; in the event the pharmaceutical products are to be imported by a government agency or a non-governmental charity organization and delivered for free, that circumstance shall be informed;

(iii) the costs of stocking and distributing the imported products.]

(b) The importer shall keep the Minister and the patent owner in [the country] as well as the exporter in the exporting WTO Member informed about relevant developments in the use of the imported products in [the country] and shall provide complementary information if requested by the Minister and the patent owner as well as the licensee in the exporting WTO Member.

[7. If pharmaceutical products are subject to marketing approval prior to their distribution in [the country], the authorities may rely on undisclosed test or other data submitted by a person other than the importer as a condition for approving the marketing of the products imported under this Section. Nevertheless, the authorities shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use.]

8. For the purposes of this Section, "pharmaceutical product" means any product, or product manufactured through a process, of the pharmaceutical sector needed to address public health problems afflicting the importing country or territory, for which a patent has been granted at least in the exporting WTO Member.

COMMENTS TO SECTION 13(A) (for a least-developing country)

1) - The comments above to section 13(A) for developing countries apply to the draft provisions for least-developed countries, *mutatis mutandis*.

2) - Because the situation of a country as an exporter only arises where a patent has been issued in the exporting country, and having in view the apparently general understanding that least-developing countries (LDCs) may lessen the level of consistency of their patent laws with the TRIPS Agreement and, until 2016, may eliminate patent protection for pharmaceutical products, even those LDCs that have already patent protection in place may exclude pharmaceutical products from patent protection.[1] Therefore, until 2016 they would be able to manufacture and export any pharmaceutical product without the need for resorting to the system established by the Decision. The same can be said as regards protection of test data concerning pharmaceutical products. Until 2016, LDCs are not under the obligation to protect those data against "me-too registrations."

Section 14

[1] They would be obliged, nevertheless, to establish a mailbox mechanism for pharmaceutical products, under Article 70.8 of the TRIPS Agreement, but not exclusive marketing rights.

It is essential, in any law on inventions, to provide for the possibility of invalidating patents not satisfying specific fundamental requirements of the law. Such a possibility should be provided for, in particular, if a country does not adopt the system in which patent applications are substantively examined.

This Section provides for a judicial procedure for the invalidation of the patent since it is preferable to entrust this delicate task to an authority independent of the one that granted the patent.

Subsection (1) states that only an "interested person" may request invalidation of a patent. In general terms, one could define an interested person as being any person who, because of the existence of the patent which does not satisfy the prescribed requirements, is hampered in the exploitation of the invention. A public authority, entrusted, for example, with the regulation of trade or consumer protection, could perhaps also qualify as an "interested person" on behalf of the public. However, in any given case, the court will have to determine whether a person is "interested" within the meaning of this provision.

The request to the court to invalidate a patent may be made in proceedings instituted for that purpose or as a counterclaim in a defense to an infringement suit initiated by the owner of the patent.

Subsection (2) lists the three grounds upon which a patent may be invalidated by the court. The first is that the specified substantive requirements prescribed in the law have not been met. The patent will be invalidated on this ground if any of the following facts are proved: what is claimed to be an invention is not an invention within the meaning of *Section 1(2);* the subject matter of the invention is excluded from patentability under *Section 1(3);* the invention claimed in the patent is not patentable under *Section 2* because it is not new, does not involve an inventive step or is not industrially applicable; the description did not disclose the invention completely or did not indicate at least one mode known to the applicant for carrying out the invention as required by *Section 4(3);* the claims are not clear and supported by the description as required by *Section 4(4);* or the drawings necessary for the understanding of the invention, required under *Section 4(5),* were not furnished. The second ground is that the person to whom the patent has been granted has no right to it. Where the application or patent was amended and the amendment should not have been allowed because it extended the disclosure beyond the scope of the initial application, the court will have to invalidate the patent to the extent that the disclosure had been extended beyond the content of the initial application. Since the ground for the partial invalidation of patents in such cases is found in *Sections 5(2)* and *9(3),* there does not seem to be a need to provide for express provisions in this regard in *Section 14.*

Invalidation

14.(1) Any interested person may request the court to invalidate a patent.

(2) The court shall invalidate the patent if the person requesting the invalidation proves that any of the requirements of Sections 1(2) and (3), 2 and 4(3), (4) and (5) is not fulfilled or if the owner of the patent is not the inventor or his successor in title.