

(4) If the invention claimed in a patent ("later patent") cannot be exploited in the country without infringing a patent granted on the basis of an application benefiting from an earlier filing or, where appropriate, priority date ("earlier patent"), and provided that the invention claimed in the later patent involves an important technical advance of considerable economic importance in relation to the invention claimed in the earlier patent, the [Registrar] [Court], upon the request of the owner of the later patent, may issue a non-voluntary license to the extent necessary to avoid infringement of the earlier patent.

(5) Where a non-voluntary license is issued under subsection (4), the [Registrar] [Court], upon the request of the owner of the earlier patent, shall issue a non-voluntary license in respect of the later patent.

(6) In the case of a request for the issuance of a non-voluntary license under subsections (4) and (5), subsection (2) shall apply *mutatis mutandis* with the proviso that no time limit needs to be fixed.

(7) In the case of a non-voluntary license issued under subsection (4), the transfer may be made only with the later patent, or, in the case of a non-voluntary license issued under subsection (5), only with the earlier patent.

(8) The request for the issuance of a non-voluntary license shall be subject to payment of the prescribed fee.

(9) Section 12(2) to (10) shall apply *mutatis mutandis*.

### *Section 13A*

The Declaration on the TRIPS Agreement and Public Health adopted on November 14, 2001 at the Fourth Session of the Ministerial Conference of the World Trade Organization (WTO), in Doha, (WT/MIN(01)/DEC/W/2), affirmed that the TRIPS Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all. In this context, the right of WTO Members to use to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose, including the use of compulsory licensing, was reaffirmed.

However, it was also recognized that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. For this reason, the TRIPS Council was instructed, in paragraph 6 of the Declaration, to find an expeditious solution to this problem and to report to the General Council before the end of 2002. In accordance with the said request, the WTO General Council, on August 30, 2003, adopted a Decision on the implementation of paragraph 6 of the Doha Declaration (WTO doc. WT/L/540). The Decision provides for interim waivers of Members' obligations under Article 31(f) and Article 31(h) of the TRIPS Agreement. Those two provisions could effectively limit the ability of WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector to import pharmaceutical products from countries where they were patented. The Decision now allows any WTO Member to export, within the terms set out in the Decision, pharmaceutical products made under compulsory licences to those countries. The Decision will remain in force for each Member until a formal amendment to the TRIPS Agreement replacing its provisions takes effect for that Member. So far, such an amendment has not been adopted.

The following provisions of Section 13A aim at introducing in WIPO Draft Provisions on Industrial Property a number of legal provisions implementing the aforementioned Decision. Those draft provisions, as well as the attached commentary, have the purpose of assisting WIPO Members in implementing the Decision, and they should not be seen as an interpretation of the Decision or of the TRIPS Agreement, for the WIPO Secretariat has not such a mandate.

Besides, it is a matter for each WTO Member to decide the manner of implementing the Decision in accordance to its legal system and practice. The following draft provisions have adopted a more detailed treatment of the matter, in line with the style of the WIPO draft provisions on compulsory licenses, which they aim at supplementing. However, WTO Members are free to choose a simpler approach, by, for example, just incorporating the provisions of the Decision into national law, which would give it direct application. This solution would require a reference to the Decision in the national statutory provision reflecting Article 31(f) (for example: "compulsory licenses shall be granted predominantly for the supply of the domestic market of [name of country], except where otherwise permitted under 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 access to health."), as well as in the provision reflecting Article 31(h) (for example: "the right holder shall be paid

adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization, without prejudice to the relevant provisions of 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 access to health.”). Nevertheless, in this event, the national statute of the importing Member should supplement the Decision by introducing measures against deviation and re-exportation in the event there is no patent in force in that Member. This is necessary in view of the fact that paragraph 5 of the Decision provides that Members shall use “the [enforcement] means already required to be available under the TRIPS Agreement.” If no patent is in force in the importing country, it follows that there are no measures in place to sanction deviation or re-exportation of unpatented products in that country.



*Draft provisions for a developing country Member of the WTO*

**(I) As an exporter**

1. Where a pharmaceutical product is covered by a patent and the Minister<sup>1)</sup> receives a request by the competent authority of another WTO Member<sup>2)</sup> 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;<sup>3)</sup> and
- (b) the Minister is satisfied<sup>4)</sup> 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 the pharmaceutical product in question 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 Declaration on the TRIPS Agreement and Public Health ("the Decision").<sup>5)</sup>

2. The non-voluntary license or authorization<sup>6) 7)</sup> granted by the Minister shall contain the following conditions:

- (a) only the amount notified and requested by the eligible importing Member(s) may be manufactured under the license and the entirety of this production shall be exported to the requesting Member;
- (b) products produced under the licence shall 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.<sup>8) 9)</sup>

3. The Minister shall notify the Council for TRIPS of the grant of the license, including the conditions attached to it, without undue delay.<sup>10)</sup> 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.<sup>11)</sup>

4. The licensee shall be responsible for taking any reasonable measures to avoid trade diversion and exportation of the products produced under the non-voluntary license to other destinations. Any act that constitutes trade diversion leading to exportation of the products produced under the non-voluntary license to destinations other than that (or those) specified in the non-voluntary license 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.<sup>12)</sup>

[(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 shares the health problem in question. If such 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 Section 12(7), which shall not apply,<sup>13)</sup> 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.<sup>14)</sup>

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 the public health problems, as recognized in paragraph 1 of the Declaration on the TRIPS Agreement and Public Health (WT/MIN(01)/DEC/2), afflicting the eligible importing WTO Member;

(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 using the system established by the Decision ("the system").

## (II) As an importer



1. Where a pharmaceutical product is covered by a patent<sup>15)</sup> the Minister may authorize its importation from another WTO Member under the system, provided the following conditions are met:

(a) the competent authority has previously made a notification to the TRIPS Council of [the country]'s intention to use the system as an importer; and

(b) the Minister has previously 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 country] has established that it has insufficient or no manufacturing capacities in the pharmaceutical sector for the product(s) in question; and

(iii) 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.<sup>16)</sup>

[(d) the Minister is satisfied that the pharmaceutical products to be imported are needed for attending an existing or potential situation of national emergency or other circumstances of extreme urgency.<sup>17)</sup>]

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 importer shall be responsible for taking reasonable measures to avoid trade diversion and re-exportation of the products imported under the system. Any act that constitutes trade diversion leading to re-exportation of the products imported under the non-voluntary license shall be deemed a patent infringement, 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*.]<sup>19)</sup>

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,<sup>20)</sup> and Section 12(2), which shall not apply in respect of those products for which remuneration in accordance with Section 13A(I)(5) is paid in the exporting WTO Member.

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:<sup>22)</sup>

(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.]<sup>23)</sup>

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 Samoa, for which a patent has been granted at least in the exporting WTO Member.<sup>24)</sup>



# COMMENTS TO SECTION 13(A) (for a developing country)

<sup>1)</sup> - It is suggested that the Minister of Health could be the authority competent to oversee the matter of compulsory licenses under the WTO Ministerial Conference Declaration on the TRIPS Agreement and Public Health ("the Declaration") and the Decision of the WTO General Council of August 30, 2003 on the Implementation of Paragraph 6 of that Declaration ("the Decision"). The health authorities are perhaps in a better position to assess the availability of pharmaceutical products, to control their production and distribution and to verify the technical capacity of the licensee to manufacture the licensed invention under acceptable standards of quality and safety. But countries are free in that regard: they may prefer to keep the competence of granting compulsory licenses within the Ministry or other authority in charge of industrial property matters or even with courts (although courts may lack the technical skills and the procedural flexibility to handle urgent matters in the health sector).

<sup>2)</sup> - It is understood that all the information necessary for the Minister to take the decision of granting a compulsory license is to be supplied by the authorities of the WTO Member requesting the importation. The proposed provision does not oblige the Minister to grant the license under the sole conditions prescribed in the Decision. It is a matter for national legislation to decide on any limitation of the Minister's discretion.

<sup>3)</sup> - It is the obligation of the exporting WTO Member to verify whether the requesting country is indeed an eligible importing WTO Member. For that verification, the exporting WTO Member can rely on one out of two objective conditions: that the requesting WTO Member is a least-developed country WTO Member ("LDC"); or that it is a WTO Member and it fulfils the conditions set out in the Decision, namely that it has notified the TRIPS Council of its intention to use the system as an importer (Decision, paragraph 1(b)) and that it has declared that it lacks sufficient manufacturing capacity (in the terms established by the Annex to the Decision) — of course, the accuracy of this declaration does **not** need to be checked by the exporting country authority. The responsibility for its accuracy belongs exclusively to the requesting importing WTO Member.

On the other hand, it should be noted that the notification by the importing (requesting) country of its intention to use the scheme established by the Decision may be made *in abstracto*, that is, it may be made even before the concrete need for importing pharmaceutical products manufactured in another country under a compulsory license actually appears.

<sup>4)</sup> - As mentioned above, the authority of the exporting WTO Member granting the compulsory license that deviates from the conditions of Article 31(f) (under the waiver) may be ultimately deemed responsible for any failure in meeting the conditions established for the grant of the waiver. Therefore, the compulsory license should be granted only upon satisfaction of the granting authority that all conditions the exporting country must meet have actually been met. However, as noted above, some of the conditions are to be met by the importing Member, and thus the authority in the exporting Member may rely on information received along with the request for granting the non-voluntary license for exportation purposes.

<sup>5)</sup> - These conditions reflect the provisions of paragraph 2(a) of the Decision.



- <sup>6)</sup> - It seems that the Decision does not deal with the situation of those developing country WTO Members that, under Article 65.4 of the TRIPS Agreement, have postponed the implementation of the provisions on product patents of Section 5 of Part II, and are therefore obliged to grant exclusive marketing rights for pharmaceutical products.
- <sup>7)</sup> - These provisions apply both in case a compulsory license is granted formally and in case a compulsory license is implied, in those countries where the government or persons authorized by the government may use patented inventions without the authorization of the patent owner, but provided all the conditions of Article 31 of the TRIPS Agreement are met. Actually, even though the Decision uses the term "compulsory license," the TRIPS Agreement does not employ it.
- <sup>8)</sup> - These conditions reflect the provisions of paragraph 2(b) of the Decision.
- <sup>9)</sup> - The waiver of the obligations under Article 31(f) of the TRIPS Agreement and the mechanism set out by the Decision should be used to encourage technology transfer in the pharmaceutical sector, in order to foster competition and increase access to pharmaceutical products. The authorities of the exporting and the importing countries, in coordination with the licensee in the exporting country, may therefore wish to reflect the provisions of paragraph 7 of the Decision and include as an additional condition to the compulsory license the obligation for the licensee to transfer to an entity designated by the competent authority in the importing Member the necessary technology for manufacturing the patented product, including methods for monitoring and maintaining effective quality controls.
- <sup>10)</sup> - The Decision does not stipulate any time limit for the notification of the license to be made to the TRIPS Council. But for the sake of transparency and legal security of patent owners and users, that notification should be made without undue delay.
- <sup>11)</sup> - These provisions reflect the obligations of the exporting Member under paragraph 2(c) of the Decision.
- <sup>12)</sup> - The waiver of the provisions of Article 31(f) of the TRIPS Agreement (and, to some extent, of those of Article 31(h)) is granted on the condition that the pharmaceutical products are exported for meeting the health needs of countries that, because of their lack of manufacturing capacity, could not resort to the compulsory license mechanism (Decision, paragraph 2). Any failure to meet that condition eliminates the justification for the waiver, which is automatically withdrawn, and thus becomes an infringement of patent rights. The most meaningful measure to avoid diversion of pharmaceutical products manufactured and sold according to the mechanism set out by the Decision would be border measures, which are not mandatory for patent right infringements (TRIPS, Article 51). But Members may wish to enable those measures to ensure that the conditions established by the Decision are complied with. In that case, sanctions would also be administrative. Governments might also envisage the possibility of other administrative sanctions, such as withdrawing the permission of the infringer of manufacturing and distributing pharmaceutical products, activity which in many countries requires a governmental authorization. On the other hand, and because the grounds for granting the compulsory license may remain unattended, simply canceling it would leave the problems of access to the pharmaceutical products unsolved. Therefore, the Minister retains the right of transferring the license to a third party.

<sup>13)</sup> - Sections 12 and 13 of the WIPO Draft Industrial Property Act implement the conditions that compulsory licenses and government authorizations must respect under Article 31 of the TRIPS Agreement — which, under paragraph 2(a)(iii) of the Decision, remains the provision controlling compulsory licenses. However, paragraph 2 of the Decision provides for a general waiver of Article 31(f), which Section 13(A)(I)(5) reflects.

<sup>14)</sup> - As far as Article 31(h) is concerned, there is no waiver as regards the compulsory license for exportation purposes, but rather a qualification of the remuneration to be paid, which is to be calculated taking into account the economic value of the use to the importing Member (Decision, paragraph 3). The TRIPS Agreement offers no directions on how to determine such an economic value. However, Section 13A(II)(6)(a) provides some elements that may help the compulsory license granting authority in the exporting country to evaluate that use in the importing country.

<sup>15)</sup> - The situation of a country with no capacity or insufficient capacity to manufacture pharmaceutical products can be addressed in two different manners. If the imported pharmaceutical products are not covered by a patent in the importing country, there is no practical need to take patent-related legislative action. The importing country would just need to adopt legislative measures to sanction unauthorized deviation or re-exportation of the unpatented imported products. In that situation, the importing Member will provide the exporting Member with information necessary for the latter to follow the mandatory provisions of the Decision. But if a patent covers the imported products, and because in that event the importing Member must grant a compulsory license (Decision, paragraph 2(a)(iii)), the legal solution will depend on the level of details with which the national law deals with compulsory licenses. If national law is sufficiently flexible to accommodate the conditions set out by the Decision for the importing countries, no legislative action will be necessary. But if the national law is more specific (like the WIPO Draft Industrial Property Act), legislative action may be necessary. Moreover, in those countries where the infringement of patent rights is not only a civil violation, but also a criminal offence, it may be necessary to adopt a specific provision on the deviation or re-exportation of products imported under the Decision (*nullum crimen sine lege*). Actually, the mechanism set out by the Decision stems from the existence of a valid patent in the exporting country only, and in view of the prohibition of manufacturing a patented product with the main or exclusive intention of exporting it, under Article 31(f). Therefore, even a country where there is no valid patent may be faced with the problem of lack of availability of the needed products and the impossibility of importing them from a country where a patent has been granted. In this context, four different situations may arise:

a) In the exporting country (country A) there is no patent and a patent exists in the importing country (country B); in this event, if the products that are covered by a patent in country B are available in country A (but not in B), a compulsory license may be granted in country B for the purpose of importing the patent products from country A or for the local production in country B of the patented products; in that situation country B may not resort to parallel importation, even if its legislation provides for international exhaustion, because the rights of the patented goods have not been exhausted in country A — where a patent has not been granted.

b) In country A there is a patent and in country B there is no patent; if the patented products produced by the patent owner or with his consent are available in country A at reasonable prices, quantities and quality, country B will simply import those; but if they are not available