

**Exportation of Drugs under Compulsory Licenses:
The WTO Decision on Implementation of Paragraph 6 of the Doha Declaration
on the TRIPS Agreement and Public Health**

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On August 30, 2003 the World Trade Organization's General Council issued an important decision entitled "Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health" (the Decision). As a key event in the lead-up to the Fifth Ministerial Conference of the World Trade Organization (WTO) in Cancún, Mexico, September 10-14, 2003, the Decision was widely reported in the press but in ambiguous and sometimes contradictory terms.

This Note will: (1) provide a limited amount of context; (2) summarize the Decision and the accompanying statement of the Chairperson; and (3) provide observations on these texts with a view to facilitating understanding and implementation.¹

The Context

The Decision fulfilled an express mandate given to the Council for TRIPS in paragraph 6 of the Doha Ministerial Conference's "Declaration on the TRIPS Agreement and Public Health": to find "an expeditious solution" to the problems that could be faced by WTO members² "with insufficient or no manufacturing capacities in the pharmaceutical sector in making effective use of compulsory licensing under the TRIPS Agreement."³

¹ This Note has benefited from comments by Carsten Fink, Juan Rovira, Yolanda Tayler, Philip Hedger, and Raj Soopramanien, all of the World Bank, Prof. Frederick M. Abbott, Florida State University College of Law, Ellen 't Hoen and Pascale Boulet, Medecins sans Frontieres, and information provided by Dilip G. Shah, Indian Pharmaceutical Alliance, and William F. Haddad, BIOGENERICS. The author alone is responsible for the views expressed in this Note.

Notes in this Series are intended to provide information on current legal issues relevant to the fight against HIV/AIDS in developing countries. For purposes of readability, textual references and citations of authorities are minimized, and matters expressed in fine detail in a legal text may be treated in severely simplified fashion. Comments on these Notes are invited and subsequent versions may be issued in light of comments received. Please address comments to: rvanpuymbroeck@worldbank.org.

² In the remainder of this Note, the expressions "WTO members" and "countries" will be used interchangeably, it being understood that for the purposes of this Note "countries" refers to members of the WTO.

³ The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) is one of the Multilateral Agreements annexed to the Agreement Establishing the World Trade Organization that is binding on all WTO members.

To understand the problem, we must first go back to the TRIPS Agreement itself.

A compulsory license is a legal vehicle whereby a producer or an importer is granted the right to produce or to import a product without authorization of the patent or rights holder in the country of production or importation. Since compulsory licenses are a means to deprive the patent or rights holder of the monopoly granted by the patent, their issuance is the subject of detailed conditions laid out in Article 31 of the TRIPS Agreement.

Among these conditions, the following are especially relevant for current purposes:

- domestic law must make provision for the grant of compulsory licenses;
- prior to granting a compulsory license, the government intending to issue it must first have made efforts to negotiate authorization from the rights holder on reasonable terms and conditions and for a reasonable period of time. However, the government may dispense with this requirement in the case of a national emergency, other circumstances of extreme urgency, or public non-commercial use;
- the use authorized by the compulsory license is to be “predominantly for the supply of the domestic market”; and
- adequate remuneration must be paid to the rights holder.

Of these, the one that caused most uncertainty was the predominant domestic supply requirement, and it was this restriction that the Decision was principally called to address. The other conditions mentioned above also figure in the solution that was finally adopted, and will also be discussed below.

The latest round of multilateral trade negotiations was started at Doha, Qatar, in November 2001. By this time, the dire public health situation in many developing countries, especially with respect to HIV/AIDS and other communicable diseases, had built up strong pressures for an accommodation of the international trade law regime to the urgent need for greater access to affordable drugs. As a result, the Doha Ministerial Conference adopted a “Declaration on the TRIPS Agreement and Public Health” (Declaration or Doha Declaration), which was widely hailed as a ringing confirmation of the primacy of public health requirements over corporate interests, no mean feat in light of how other quality of life matters (such as the environment and core labor standards) have fared under the WTO regime.

Among other things, the Declaration recognized explicitly that:

- countries should not be prevented by the TRIPS Agreement from taking measures necessary to protect public health;⁴
- the TRIPS Agreement should be interpreted and implemented in a manner that supports public health and, in particular, that promotes access to medicines for all; and
- countries have the right to use to the full the flexibility provided by the TRIPS Agreement to ensure access to medicines for all, including in particular: (i) the right to determine what constitutes a national emergency or extreme urgency; (ii) the right to establish their own regime with respect to the exhaustion of intellectual property rights⁵; and (iii) the freedom to grant compulsory licenses, as well as the freedom to determine the grounds on which they are to be granted.

In its paragraph 6, the Declaration acknowledged that Article 31 of the TRIPS Agreement could impede the effective use of the compulsory license mechanism to cover the import needs of countries with no or limited manufacturing capability, and the Council for TRIPS was charged with finding an expeditious solution to the problem.

After two and a half years of work, after the originally imposed deadline of end December 2002 was well passed, a compromise acceptable to the developed countries and the developing countries was finally achieved by the end of August 2003 and adopted as a decision of the WTO's General Council.⁶

While the history of the process by which this result was reached is important and revelatory of how international trade diplomacy works in the pharmaceutical sector, the remainder of this Note will be principally devoted to a textual analysis of the Decision and an initial assessment. Most participants and observers agree that, regardless of its merits or demerits, the Decision constitutes the basis for going forward, and the task now is to make it work.

The Decision

Recognizing explicitly that for pharmaceutical products exceptional circumstances exist to justify waivers of the predominant domestic supply requirement and the adequate remuneration requirement of Article 31 of the

⁴ This is also reflected expressly in Art. 8.1 ("Principles") of the TRIPS Agreement.

⁵ Exhaustion of intellectual property rights is deemed to take place when the rights holder has been compensated in a legitimate manner, such as by sale of the product. Countries that adopt a regional or international approach to exhaustion allow the importation and sale of such products without requiring the consent of the rights holder in their territory.

⁶ The General Council, which is composed of the representatives of all member countries, exercises the functions of the Ministerial Conference when the latter is not in session, as well as other specific functions assigned to it under the WTO Agreement.

TRIPS Agreement, the Decision sets up a system that both the exporting country and the importing country need to follow in order to implement these waivers.⁷

First, the waiver of the predominant domestic supply requirement.

This requirement is waived with respect to the compulsory license granted by the exporting country if the following conditions are met:

(a) the importing country must be an “eligible importing Member”, which means that it must be a least-developed country⁸, or any other member country that has notified the Council for TRIPS that it intends to use the system as an importer⁹;

(b) the eligible importing Member must provide a notification to the Council for TRIPS which contains: (i) the name and expected quantity of the product (or products) needed; (ii) confirmation that it has established (in one of the ways set out in the annex to the Decision) that it has no or insufficient manufacturing capacity for the product in question—but least-developed countries are exempt from this requirement; and (iii) confirmation that the country has granted or will grant a compulsory license in accordance with Article 31 of the TRIPS Agreement if the pharmaceutical product is on-patent in its territory;

(c) the exporting country must notify the Council for TRIPS of the grant of the compulsory license, including the conditions attached to it (see below), and providing information about the licensee, the product(s) and the quantity for which the license was granted, the country of destination, the duration of the license; and the website that provides specified information about the license (see below); and

(d) the compulsory license must be subject to the following conditions: (i) only the amount of product necessary in the eligible importing country may be produced under the license and all that production must be exported to that country; (ii) all products so produced must be clearly identified under the system set up under this Decision through specific labeling or marking—the products should be distinguished through special packaging and/or special coloring or shaping of the products themselves, provided the distinction is feasible and has

⁷ It may be useful to observe that the predominant supply of the domestic market requirement does not apply to compulsory licenses granted to remedy anti-competitive practices (TRIPS Agreement, Art. 31 (k)). A discussion of other flexibilities available under the TRIPS Agreement (e.g. parallel imports) is beyond the scope of this Note.

⁸ The designation “least-developed country” refers to a UN classification that is recognized by the WTO. Currently 49 countries are so designated by the UN, and 32 of them are WTO members. See http://www.wto.org/english/thewto_e/whatis_e/tif_e/org7_e.htm and the Appendix to this Note.

⁹ Countries may also notify the WTO that they will use the system only in a limited way, such as for example only with respect to cases of national emergency.

no significant impact on the price; and (iii) prior to shipment, the licensee must post on a website (which may be a WTO website to be set up for the purpose) the quantities being supplied to each destination and the distinguishing features of the product.

Second, there is the matter of the payment of adequate remuneration to the rights holder.

This obligation (contained in Article 31 of the TRIPS Agreement) is waived in the importing country provided such remuneration was paid in the exporting country. The Decision specifies that the remuneration to be paid to the rights holder in the country of export must take into account “the economic value to the importing country of the use that was authorized in the exporting country”.

While the above-described mechanism constitutes the essence of the Decision, there are some supplemental provisions and requirements that are worthy of note:

- The Decision covers not only the patented products (the products that carry the brand name) but also the active ingredients necessary for their manufacture, as well as diagnostic kits necessary for their use.
- Importing countries using the system must take reasonable measures (within their means and proportionate to their administrative capacities and the risk of trade diversion) to prevent re-exportation, and all WTO members must provide effective legal means to prevent the importation and sale of goods produced under the system which are the subject of trade diversion.
- In an express acknowledgment of the desirability of economies of scale, the predominant domestic supply requirement is waived in the case of developing or least developed countries that are members of a regional trade agreement (sanctioned by the WTO) where at least half of the members presently are least developed countries. The waiver is limited to the extent necessary to enable exportation to the members of the group.

More generally, the Decision also contains provisions encouraging the development of regional patent regimes, technology transfer, technical assistance and capacity building. The system established by the Decision is to be reviewed annually by the Council for TRIPS, which must report on it to the General Council, and work is to be started before the end of 2003 on a formal amendment of the TRIPS Agreement based “where appropriate” on the Decision.

An Annex to the Decision provides that least-developed countries are automatically deemed to have no or insufficient manufacturing capacity in the pharmaceutical sector and provides guidelines to be used by other developing

countries in establishing that they have no or insufficient manufacturing capacity.

The Accompanying Statement of the Chairperson

The Decision is accompanied by an important, formal statement of the Chairperson of the WTO's General Council (Statement). The Statement is intended to be part of the official record and purports to represent key understandings of the member countries with respect to the Decision and the way in which it is to be interpreted and implemented.

First, the Statement underlines that the new system is to be used in good faith. It is to be used to protect public health and should not be used as an instrument to pursue industrial or commercial policy objectives.

Second, the Statement deals with the important subject of trade diversion: the beneficent purpose of the Decision would be defeated if products put into international commerce under these arrangements end up being re-exported to countries other than the intended destinations, especially of course developed countries. The Statement provides best practice guidelines for dealing with this problem.

Third, issues arising under the Decision are to be resolved expeditiously and amicably, and to this end:

- the notifications of importing developing countries should contain information on how the country established that it has no or limited manufacturing capacity in the pharmaceutical sector;
- all notifications made under the system will be brought to the attention of the TRIPS Council at its next meeting;
- any member country may bring up issues to the TRIPS Council "for expeditious review" and with a view to "taking appropriate action";
- in addition to bringing issues to the TRIPS Council, any member concerned that the Decision has not been "fully" complied with may utilize the good offices of the WTO's Director General or the Chair of the TRIPS Council in order to find a mutually acceptable solution.

Finally, the Statement names the industrialized countries that have agreed to opt out of the system as importers; the countries that are candidates for accession to the EU who have agreed that they will only use the system as importers in situations of national emergency or extreme urgency, and that they will opt out of the system as importers upon their accession to the EU; and certain other countries (including World Bank borrowers Mexico and Turkey) that have

declared they will only use the system as importers in situations of national emergency or extreme urgency.

Observations

On the positive side, the Decision accomplishes some useful things.

First of all, it applies to public health problems in general in developing and least-developed countries, not just to those related to HIV/AIDS, tuberculosis, malaria and other epidemics.

The system established by the Decision is readily available to all least-developed countries, and to those other member countries of the WTO that notify the Council for TRIPS of their intention to use the system as an importer.

Provided the system laid out in the Decision is properly applied, the imprecise but real requirement of the TRIPS Agreement that the production of a generic product under a compulsory license has to be predominantly for the supply of the domestic market is eliminated. Thus, under the conditions laid out in the Decision, countries (including developed countries) now have the green light to produce generics for export under compulsory license to help address the grave public health problems of developing and least-developed countries.

The Decision also avoids confusion on the question of whether adequate remuneration would have to be paid twice, i.e. once in the producing/exporting country and once in the importing country –the payment of remuneration in the importing country is waived.

As a by-product, the Decision also deals with the problem of trade diversion and the problems that are created when parallel imports into developing countries, or patented products sold under a tiered or equity pricing scheme, find their way back into higher income markets. While other ways are available to handle the issue, perhaps the provisions of the Decision and the Chairperson's Statement on the point may help pave the way for a wider application of tiered or equity pricing of patent-protected products.

Predictability of outcomes makes markets more efficient and stimulates economic activity. To the extent the mechanics of the system set up by the Decision function well and do not raise costs to any significant extent, the system has the potential of contributing to greater availability of lower cost drugs in countries where they are needed.

However, in the previous sentence also lurks the challenge. As should be readily apparent from the above description of the new system, it is detailed and relatively complex. And in the shadows of complexity, opportunities for misapplication abound.

It is difficult to say that the system represents an “expeditious solution”, as envisaged in the Doha Declaration. Expeditious comes from expedition, meaning efficient promptness.¹⁰ The system builds in obvious delays, as well as delays that may not be so obvious. It also contains a number of measures that raise transaction costs.

First, let us consider the possibilities for delay.

The system presupposes that countries’ legislations provide for compulsory licenses. This may not be true for a number of countries, and even those whose patent law currently provides for this public policy instrument may have to adapt their legislation to ensure compliance with the Decision. While this may be a quick process in a few instances, in other countries the delays involved could be significant.

Second, compulsory licenses may have to be obtained in both the exporting and the importing countries. While the requirement is clear for the exporting country, the requirement only plays for the importing country if the product is on-patent in its territory. While it is sometimes claimed that few pharmaceutical products are patented in developing countries, and hence there would rarely be a need for the issuance of a compulsory license in the importing country, this is something that will need to be checked in each instance. A legal team of *Médecins sans Frontières* (MSF) did a survey on the patent status of antiretrovirals in six Anglophone and sixteen Francophone countries of Sub-Sahara Africa, and it found patents on ARVs in all of them.¹¹ Also according to MSF, in South Africa 13 out of 15 antiretroviral treatments are covered by patents.¹²

While the TRIPS Agreement requirement of prior negotiations with the rights holder has been done away with, and hence valuable time is saved, countries will have to design administrative processes for the grant and administration of compulsory licenses, and for the making of the necessary notifications to the TRIPS Council. Complying with the applicable procedures will inevitably take time.

¹⁰ Webster’s Third New International Dictionary, Unabridged (1961, 1993).

¹¹ See *Medecins sans Frontieres, Drug Patents under the Spotlight*, Annex A.

¹² *Medecins sans Frontieres, “Enduring Myths” in Doha Derailed* at <http://www.accessmed-msf.org/documents/cancunbriefing>.

There is uncertainty about just how much interference from the WTO and its members, and consequent delay, may result from the notification process. Footnote 2 to the Decision explicitly states that prior approval of the notifications is not required for countries to use the system. That is simple enough. However, the early notification process and the information to be posted on a public website provide ample opportunity for scrutiny, and action, by other countries at the behest of their pharmaceutical manufacturers.

The Chairperson's accompanying Statement emphasizes that any member country may raise concerns about the implementation of the Decision to the TRIPS Council "for expeditious review, with a view to taking appropriate action." Hence, countries seeking to avail themselves of the system may be called upon to explain and defend their actions, and all of this will consume time and introduce uncertainty. Uncertainty may delay, if not discourage, production decisions. If the outcome of the process should be that remedial action is requested, more time may elapse while the remedial action is being carried out.

The Statement also provides that any member country may avail itself of the good offices of the WTO Director General or the Chairperson of the TRIPS Council to find a "mutually acceptable solution" to any perceived problems. Again, while this kind of behind-the-scenes diplomacy is carried out, uncertainty and delays are likely to result.¹³

The detailed procedures laid out in the Decision will increase transaction costs, not only because action is required by two governments, but also because there will be direct costs to be borne by the generic manufacturer (the company authorized under the compulsory license).

The requirements for product differentiation are well-intended, but may lead to problems in implementation. The examples of "best practices" given in the attachment to the Chairperson's Statement run the gamut from special labeling and packaging to trademarks and special marking of capsules or shaping of pills. Particularly if modification of the shape of a pill or capsule should be insisted upon, technical issues with respect to bio-equivalence may arise, and research, engineering and production costs may be increased. These fears should not be exaggerated because the text of the Decision clearly indicates that not all measures of differentiation need to be adopted and so, for example, special packaging alone may suffice. The point here simply is that some cost (and hence price) increase may be forced upon the generic manufacturer, and that this will have an adverse effect on the realization of access to medicines for all.

¹³ The relationship between these procedures and the WTO's Understanding on Rules and Procedures Governing the Settlement of Disputes (Annex 2 to the WTO Agreement) is not clear, and may in itself become a cause of uncertainty and delay.

There are certain areas of the Decision that are unclear.

One area relates to the inclusion in the system of least-developed countries. In accordance with an express instruction in paragraph 7 of the Doha Declaration, on June 27, 2002 the Council for TRIPS issued a formal decision exempting least-developed countries from the TRIPS patent regime until January 1, 2016. Yet, the August 30, 2003 Decision applies to least-developed countries and imposes certain obligations on them.¹⁴ Presumably, this apparent contradiction can be resolved by accepting that if a least-developed country takes the position that it will avail itself of the freedom not to enforce patent rights until 2016, then it does not have to apply the Decision either.

The calculation of the compensation to the rights holder in the exporting country is likely to be another source of confusion. According to the Decision, adequate remuneration has to be paid and the amount is to be determined by taking into account the economic value to the importing country. This is a vague standard indeed and it is not at all obvious how it will be applied.

Unintended rigidities may have crept into the system that may need ironing out. While the Decision appropriately acknowledges the desirability of promoting economies of scale in the context of recognized regional trading groups, this principle should also be applicable more generally. A strict reading of the Decision would appear to point to a batch manufacturing process geared to each individual order, a sure way to make production more costly and inefficient than it needs to be.

Another point that is unclear pertains to the self-determination by a developing country that it lacks sufficient manufacturing capacity in the pharmaceutical sector and that, hence, it needs to import the drug(s) in question. Importing countries need to report on how they arrived at this determination in their notification to the TRIPS Council, and as we have seen above, other countries would appear to be able to dispute the matter.

There are also some plain drafting problems. For example, the restriction in the paragraph on regional arrangements to countries “presently” on the list of least developed countries appears to negate the possibility of countries being added to the list, or graduating from the list.

¹⁴ As discussed in the text above, under the new system a least-developed country will have to notify the Council for TRIPS of the names and expected quantities of the products to be imported. If a product is on-patent in its territory, it must also state that it has granted or intends to grant a compulsory license.

The short-term impact of the Decision remains to be seen. Canada is reportedly considering changing its applicable law to allow the manufacture for export under the Decisions. The impact of the Decision may be felt mostly after January 2005, when developing countries other than WTO-recognized least-developed countries will have to start applying the TRIPS patent regime and newly patented products will be needed as generics to ensure affordable access. This leaves some time to iron out the ambiguities in the new arrangement, and for all WTO member countries to show that they intend to apply the Decision in good faith and in the spirit of Doha. As recognized in the fourth preamble of the Decision, when countries need to import drugs to meet their public health needs, a rapid response to these needs is vitally important.¹⁵

A last comment. The Decision was reached in the momentum that built up as part of the preparations for the Cancún Ministerial Conference of the WTO. As is well known, that meeting of the trade ministers ended without consensus on a significant number of key issues. The fact that, as a result, the Cancun meeting has variously been labeled a set-back or a failure, does not, however, affect the Decision, at least not as a legal matter. The Ministerial Statement issued upon the conclusion of the Cancún meeting expressly reaffirmed all prior Doha Declarations and Decisions. So, the final conclusion must be that the Decision is what countries now have to work with to facilitate exports of pharmaceutical products manufactured under compulsory licenses and so to bring the goal of affordable medicines for all closer to realization. As said above, good faith and application of the spirit of Doha will be critical in making this happen.

¹⁵ While the Decision provides only a temporary waiver of certain Article 31 requirements until an amendment of the TRIPS Agreement is negotiated, if the new system shows that it is adequate to the task, it may well be carried over into the amendment.

Appendix

List of Least-Developing Countries that are Members of the WTO

(Source: WTO website, last consulted September 25, 2003, plus recent accessions by Cambodia and Nepal)

Angola
Bangladesh
Benin
Burkina Faso
Burundi
Cambodia
Central African Republic
Chad
Congo, Democratic Republic of the
Djibouti
Gambia
Guinea
Guinea Bissau
Haití
Lesotho
Madagascar
Malawi
Maldives
Mali
Mauritania
Mozambique
Myanmar
Nepal
Niger
Rwanda
Senegal
Sierra Leone
Solomon Islands
Tanzania
Togo
Uganda
Zambia

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