

**COMPULSORY LICENSING FOR PUBLIC HEALTH:
A GUIDE AND MODEL DOCUMENTS FOR IMPLEMENTATION OF THE
DOHA DECLARATION PARAGRAPH 6 DECISION**

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Foreword

The World Trade Organization's decision of August 30, 2003 on the implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health was intended to facilitate access to medicines in developing countries. The decision, which was the outcome of nearly two years of strenuous multilateral negotiations, was widely reported in the international press and in professional journals.

Despite all this attention, the decision has still not been used to bring affordable, life-saving medicines to countries that, judging by the severity of their public health challenges, need them desperately. This is an extraordinary fact, and one worthy of further inquiry. One reason for the lack of follow-up action may be that the subject is inherently difficult: it deals with the intersection of the law of patents, an arcane discipline, and the international trade regime – both in its legal rules and in the practical conduct of state-to-state cooperation. The recognition of this inherent complexity led to the idea of producing a guide with actual model legal instruments and draft statutory provisions to facilitate the implementation of the decision.

The project was undertaken and managed by Rudolf V. Van Puymbroeck, Lead Counsel in our Legal Advisory Services group, when he served as full-time legal adviser with the World Bank's Global HIV/AIDS Program. Professor Frederick M. Abbott, Edward Ball Eminent Scholar Professor of International Law at Florida State University College of Law, provided the drafts of the model legal documents and detailed commentary.

In the summer of 2004 an advanced draft was circulated for comment to a large number of legal practitioners, academics, international organizations, non-governmental organizations, representatives of the research-based pharmaceutical industry and of generic pharmaceutical manufacturers, and far-flung specialized staff of the World Bank. Much useful feedback was received and duly incorporated. The result is the Guide that you now have before you.

I sincerely hope that it will serve policy-makers and their legal advisers in many developing countries in confronting effectively, and ultimately overcoming, the significant public health challenges they face, including, especially, the scourge of HIV/AIDS.

Roberto Dañino,
Senior Vice President and General Counsel,
The World Bank

Washington, D.C.
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Abstract

The Doha Declaration on the TRIPS Agreement and Public Health (in its paragraph 6) recognized that developing countries with insufficient or no manufacturing capacity in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. The WTO's decision of August 30, 2003 set up a system intended to overcome these difficulties. The present work is a guide to the implementation of that system. The first part gives the reader an understanding of the issues involved; the second part provides model documents for use by governments. Four model instruments of notification are included: three for notification of the WTO as required by the Decision and one for notification of the patent or right holder pursuant to Article 31 of the TRIPS Agreement. Since most countries will have to amend their legislation, typically their patent law, to implement the system, model amendment provisions have been provided both for exporting countries and for importing countries. All model documents contain their own detailed commentary.

Acknowledgements

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We wish to dedicate a special word of gratitude to two individuals without whom this work would not have been possible.

Dr. Debrework Zewdie, Director of the World Bank's Global HIV/AIDS Program, gave Rudolf V. Van Puymbroeck the opportunity of a year-long immersion in the legal issues associated with HIV/AIDS, and it was during this time that the project was conceived and initiated.

Critical financing for this work, and for the larger enterprise of initiating work on legal reform for effective action against HIV/AIDS, was provided by James D. Wolfensohn, president of the World Bank, who, as usual, was one step ahead of the rest of us in diagnosing the problem and contributing to the solution.

INTRODUCTION

Background

In its 4th *Global Report* UNAIDS draws attention to the abysmal rate of treatment for HIV/AIDS in low- and middle-income countries: of the 5 to 6 million people urgently in need of antiretroviral medicines, only some 400,000 were actually receiving them at the end of 2003.¹

There are many and highly diverse reasons why such an extraordinarily large number of people in developing countries who require treatment are not receiving it;² the lack of availability and the high cost of medicines to treat HIV/AIDS and associated opportunistic infections are two of them.³

Because of the downward effect on prices resulting from the introduction of generic drugs in pharmaceutical markets,⁴ the impact of patents on the price of HIV/AIDS-

¹ UNAIDS, *2004 Report on the Global AIDS Epidemic* at 101 (UNAIDS 2004) (hereinafter UNAIDS, *4th Global Report*). See also World Health Organization, *The World Health Report 2004* at 7 (WHO 2004) (pointing out, among other things, that treatment coverage for the Africa Region is only 2 %). A joint media release of UNAIDS, WHO, GFATM, and the U.S. Government dated January 26, 2005 put the number of individuals receiving antiretroviral treatment at the end of 2004 at 700,000 (available at <http://www.unaids.org/en/media>).

² See generally WHO, *The World Health Report 2004*, *supra* n. 1; WHO and UNAIDS, *Treating 3 Million by 2005: Making it Happen* (WHO 2003). See also The World Bank, *The Millennium Development Goals for Health: Rising to the Challenges*, Part II (World Bank 2004) (hereinafter *Rising to the Challenges*).

³ UNICEF, UNAIDS, WHO, and Médecins sans Frontières, *Sources and prices of selected medicines and diagnostics for people living with HIV/AIDS* at 1 (“The high price of many of the HIV-related medicines and diagnostics offered by common suppliers – especially antiretroviral and anti-cancer medicines – is one of the main barriers to their availability in developing countries.”) (WHO 2004); UNAIDS, *4th Global Report*, *supra* n. 1, at 135 (“I can take these tablets, because on the salary I earn as a judge, I am able to afford their cost ... In this I exist as a living embodiment of the inequity of drug availability and access in Africa ... My presence here embodies the injustices of AIDS in Africa because, on a continent in which 290 million Africans survive on less than one US dollar a day, I can afford monthly medication costs of about US\$400 per month.” Mr. Justice Edwin Cameron, High Court of Johannesburg, South Africa). See also Sonia Ehrlich Sachs and Jeffrey D. Sachs, *Too Poor to Stay Alive* in Kyle D. Kauffman and David L. Lindauer (eds.), *AIDS and South Africa: The Social Expression of a Pandemic* at 3-4 (Palgrave Macmillan 2004); Robert Lewis-Lettington and Peter Munyi, *Willingness and Ability to Use TRIPS Flexibilities: Kenya Case Study* at 13-14 (Department for International Development 2004); Robert Lewis-Lettington and Chikosa Banda, *A Survey of Policy and Practice on the Use of Access to Medicines-Related TRIPS Flexibilities in Malawi* at 15 (Department for International Development 2004).

⁴ Commission on Intellectual Property Rights, *Integrating Intellectual Property Rights and Development Policy* at 37 (Sept. 2002); Médecins Sans Frontières, *Surmounting Challenges: Procurement of Antiretroviral Medicines in Low- and Middle-Income Countries* at 7-8 (Médecins Sans Frontières, WHO, UNAIDS 2003). As noted in these studies and others, competition from generic manufacturers is not the only reason why prices of antiretrovirals have come down. Other important factors are: (i) government policies (particularly with respect to procurement, taxation, local production, and subsidies); (ii) deep price discounts by the major pharmaceutical companies (especially since the launching of the U.N.-sponsored Accelerating Access Initiative in May 2000) and medicine donation programs; (iii) private Foundation initiatives (e.g. the Clinton Foundation HIV/AIDS Initiative, the Bill and Melinda Gates Foundation’s Global Health Programs); and (iv) increased public attention and advocacy. See, also, The World Bank, *Rising to the Challenges*, *supra* n. 2, at 117-125. Facilitating policies and programs of international

related medicines and related supplies, and essential medicines in general, has come under increased scrutiny.

As most countries are members of the World Trade Organization (“WTO”), the patent regime of the WTO’s Agreement on Trade-Related Aspects of Intellectual Property Rights (“TRIPS Agreement”) provides in effect a global standard.⁵ It contains important flexibilities, which have been clarified and expanded in the WTO’s 2001 Declaration on the TRIPS Agreement and Public Health (“Doha Declaration”)⁶ and its Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health of August 30, 2003 (“Paragraph 6 Decision” or “the Decision”).⁷

The international community has reacted favorably to the Doha Declaration and the Decision. The World Health Assembly, the highest organ of the World Health Organization, has adopted resolutions urging all member states to adapt national legislation, whenever necessary, to use “to the full” the flexibilities contained in the TRIPS Agreement.⁸ A number of countries are now preparing the necessary legislative steps to implement the Doha Declaration and the Paragraph 6 Decision, and some have already done so.⁹

This Guide has been prepared to facilitate the implementation of the Decision.

organizations (e.g. WHO’s Pre-Qualification Scheme for HIV Drugs, the World Bank’s Multi-Country and Multi-Sector HIV-AIDS Programs) and the establishment and operation of the Global Fund to Fight AIDS, Tuberculosis and Malaria, played important supporting roles.

⁵ TRIPS Agreement, Part II, Section 5 (available at <http://docsonline.wto.org>).

⁶ WT/MIN(01)/DEC/2, available at

http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm.

⁷ IP/C/W/405, available at http://www.wto.org/english/tratop_e/trips_e/t_news_e.htm.

⁸ Resolutions WHA56.27 (2003) and WHA57.14 (2004), available at <http://www.who.int/governance/en/>.

⁹ On May 14, 2004, Canada enacted Bill C-9 to amend the Patent Act and the Food and Drugs Act with the express purpose of facilitating implementation of the Paragraph 6 Decision (hereafter referred to as “Bill C-9,” available at www.aidslaw.ca). In Norway, following the adoption on December 19, 2003 of an authorizing amendment of the Patents Act, the government has by Royal Decree of May 14, 2004, adopted regulations to implement the Paragraph 6 Decision (available at www.dep.no/ud/engelsk/p2500832). The government of the United Kingdom has expressed its intent to amend its patent legislation and will support an E.U.-wide resolution on the matter (Department for International Development, *Increasing access to essential medicines in the developing world: UK Government policy and plans* at 34, available at www2.dfid.gov.uk/pubs). On February 19, 2004 the ACP-EU Parliamentary Assembly adopted a Resolution that, among other things, calls upon the European Commission and member states to respect, promote, and support the implementation of the Doha Declaration and that calls on all countries with manufacturing capabilities to carry out the agreement quickly and without any further restrictions and fully respecting the Doha Declaration (paras. 21 and 25) (available at www.europarl.eu.int/intcoop/acp). On February 24, 2004, representatives of states and governments from Europe and Central Asia adopted the Dublin Declaration on Partnership to Fight HIV/AIDS in Europe and Central Asia, in which they agreed, among other things, on action to ensure early implementation of the Paragraph 6 Decision (para. 22) (available at www.eu2004.ie). On October 29, 2004 the European Commission proposed a regulation to implement the Paragraph 6 Decision (available at http://europa.eu.int/comm/trade/issues/global/medecine/pr291004_en.htm). The Netherlands published new rules on December 21, 2004 (available at www.cptech.org/ip/health), and draft amendments of the patent law are under consideration in Switzerland (available in French at www.ige.ch/F/jurinfo/documents/j10013f.pdf).

Structure

The Guide is structured as follows:

PART 1 gives a concise explanation of the Doha Declaration and its clarification of the flexibilities inherent in the TRIPS Agreement patent regime. It also lays out the system of substantive and procedural requirements established by the Decision (“the System”) in sufficient detail so as to provide a proper context for the model documents presented in PART 2.

PART 2 provides model documents to implement the System. They consist of model notifications to the WTO and to right holders, and model legislative and regulatory provisions that may be necessary for the domestic application of the System in both exporting and importing countries. A detailed commentary is provided after each text.

The Appendices provide further resource materials. The key WTO texts that are dealt with in the Guide are the Paragraph 6 Decision, the General Council’s Chairperson’s Statement, the Doha Declaration, and Article 31 (Other Use without Authority of the Right Holder) of the TRIPS Agreement. They are reproduced in Appendices I, II, III, and IV, respectively. The newly-enacted statutory provisions of Canada, the Netherlands, and Norway, three potential exporting countries, to implement the Paragraph 6 Decision are provided in Appendices V, VI, and VII, respectively. Official explanatory notes accompanying the statutes of the Netherlands and Norway are included as well. Finally, the list of least-developed countries available on the WTO’s website is reproduced in Appendix VIII.

Caution

At the outset, it is important to state what this Guide does not do.

First, it does not engage in a discussion about the merits or demerits of intellectual property rights, of the TRIPS Agreement patent regime, or of its application in developing countries. The Guide takes as its starting point the Paragraph 6 Decision—a decision of all the WTO member countries.

Second, the Guide takes no position on the wisdom or desirability of granting a compulsory license under the Decision in any particular case. Countries vary enormously with respect to their supply situation for medicines, the policy objectives and legal framework of their intellectual property rights regime, and their public health systems and policies. Hence, whether or not a country should avail itself of the System is a matter to be decided by its authorities after careful consideration of all the circumstances.

Third, this Guide can only provide a starting point. The actual implementation of the Paragraph 6 Decision will take place within the contours of each country’s existing

legislative and regulatory framework, practice, and jurisprudence. The authorities of each country will have to work with their own legal experts to arrive at a solution that is right for their situation.

PART 1: THE DOHA DECLARATION AND THE PARAGRAPH 6 DECISION: A CONCISE EXPLANATION

Background

A compulsory license is a legal vehicle whereby a government grants to itself or to a third party the right to produce or to import a patented product without authorization of the patent holder or right holder (both are hereafter referred to as the “right holder”).¹⁰ Their issuance is the subject of detailed conditions. For WTO member countries, a mandatory set of conditions is set out in Article 31 of the TRIPS Agreement. A country’s domestic legislation may also contain other, additional conditions affecting the issuance of compulsory licenses.

Among the conditions set out in Article 31 of the TRIPS Agreement, the following are especially relevant in the context of the Paragraph 6 Decision:

- the grantee must first have made efforts, for a reasonable time, to negotiate authorization from the right holder on “reasonable commercial terms and conditions” (Art. 31(b));
- Members may dispense with this requirement, however, in the case of a “national emergency, other circumstances of extreme urgency, or public non-commercial use” (Art. 31(b));
- the use authorized by the compulsory license must be “predominantly for the supply of the domestic market” (Art. 31(f));¹¹ and
- adequate remuneration must be paid to the right holder (Art. 31(h)).¹²

As part of the launching of a new multilateral work program of reform and liberalization of trade policies at the WTO’s Ministerial Conference in Doha, Qatar, an agreement was reached among all WTO Members on the application of the TRIPS Agreement to public

¹⁰ For a fuller treatment, see The World Bank (Yolanda Tayler, ed.), *Battling AIDS: A Decision-Maker’s Guide to the Procurement of Medicines and Related Supplies* at 119 *et seq.* (World Bank 2004) (hereinafter *Battling AIDS*), available at

<http://siteresources.worldbank.org/INTPROCUREMENT/Resources/Technical-Guide-Procure-HIV-AIDS-Meds.pdf>. In this Guide, as in *Battling AIDS*, government use licenses and compulsory licenses granted to third parties are both referred to as “compulsory licenses,” unless otherwise indicated in the text.

¹¹ 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)). Thus, when an exporting Member grants a compulsory license to remedy an anti-competitive practice it does not act under the Decision because it does not take advantage of the waiver of Article 31(f) established by the Decision. It instead acts under a pre-existing right in the TRIPS Agreement to authorize exports to address anti-competitive practices. In such cases, the importing Member does not need to comply with the notification and other requirements set out in the Decision.

¹² “Adequate remuneration” is defined with respect to the circumstances of each case, “taking into account the economic value of the authorization.” (Art. 31(h))

health.¹³ This Declaration contains important provisions for the interpretation and application of Article 31 of the TRIPS Agreement.

In its paragraph 4, the Doha Declaration formally affirms that:

- “... the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health;”
- “... 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;”
- “... WTO Members [have the right] to use, to the full, the provisions of the TRIPS Agreement, which provide flexibility for this purpose.”

The Doha Declaration then explains in its paragraph 5 that, within the context of the TRIPS Agreement, “these flexibilities include:

- ... the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted;
- ... the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.”

Paragraph 6: A Problem Left Unresolved¹⁴

The Doha Declaration left an important problem unresolved. It 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” and the Ministers charged the Council for TRIPS to find “an expeditious solution” to the problem (Doha Declaration, paragraph 6).

If a developing country does not have the industrial capacity to produce a particular medicine itself under a compulsory license, or if it has insufficient capacity, it has no recourse but to import the drug. However, if it wishes to import a generic drug that is produced under compulsory license, the amount of product that is available for export is limited by the “predominantly for the supply of the domestic market” condition in paragraph (f) of Article 31 of the TRIPS Agreement.

Countries like India and Brazil, which have a domestic generics industry, constitute—by themselves—large markets, and hence the “non-predominant part” of production

¹³ The agreement was embodied in a Declaration adopted by the Ministerial Council on November 14, 2001. *Declaration on the TRIPS Agreement and Public Health*, WT/MIN (01)/DEC/2 available at http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm.

¹⁴ This section and the following draw on Rudolf V. Van Puymbroeck, *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*, available at http://www1.worldbank.org/hiv_aids/docs/GHAPnote10.03.03.pdf.

authorized under a compulsory license could still be substantial.¹⁵ Any export of that non-predominant part would not be affected by the Paragraph 6 Decision. However, that amount may not be sufficient to satisfy all needs if many developing countries start importing such drugs in large quantities, which appears to be virtually inevitable as they are faced with an ever growing need to provide access to essential medicines.

Also, companies in other countries, developing or industrialized, that have the capability to produce quality generics may wish to manufacture expressly for export to developing countries. In order to permit the flow of such medicines to developing countries, a solution to the limitations of Article 31 of the TRIPS Agreement had to be found.

The Paragraph 6 Decision

Finding a solution to this problem was not easy. After nearly two years of hard negotiations, a compromise acceptable to the industrialized and to the developing countries was finally achieved and adopted as a decision of the WTO's General Council.¹⁶

The Decision is couched in the form of the waiver of two provisions of Article 31 of the TRIPS Agreement: (a) with respect to the exporting country, a waiver of the predominantly-for-the-domestic-market limitation; and (b) with respect to the importing country, a waiver of the adequate remuneration requirement. There is also a specific waiver of the former of these provisions, together with certain other flexibilities, for certain regional trade arrangements.

While the full text of the Decision should be consulted for all particulars, the system that both the exporting country and the importing country need to apply in order to benefit from the waivers can be summarized as follows.¹⁷

Waiver of the predominant domestic supply requirement

The predominant domestic supply requirement is waived with respect to the compulsory license granted by the exporting country if the following conditions are met:

¹⁵ The TRIPS Agreement patent regime became applicable to India as of January 1, 2005. Brazil amended its law to provide for pharmaceutical product patent protection effective May 15, 1997.

¹⁶ The General Council, which is composed of representatives of all WTO member countries, exercises the functions of the Ministerial Council when the latter is not in session, as well as other functions assigned to it under the WTO Agreement.

¹⁷ The Decision is available at <http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm>. For ease of reference, the Decision and the Chairperson's Statement are also provided in Appendices I and II, respectively. Extensive treatment of the Decision and interpretative guidance may be found in, *inter alia*, Frederick M. Abbott, *The Medicines Decision: The Political Economy of World Pharmaceutical Trade and the Protection of Public Health*, 99 Am. J. of Intl. L. (forthcoming 2005), Carlos M. Correa, *Implementation of the WTO General Council Decision on paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health* (WHO, EDM Series No. 16, 2004), Paul Vandoren and Jean Charles Van Eeckhoutte, *The WTO Decision on Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: Making it Work*, 6 J. World Intellectual Property, 779 (2003).

(a) the importing country must be an “eligible importing Member”, which means that it must be a least-developed country,¹⁸ or any other member country of the WTO that has notified the Council for TRIPS that it intends to use the system as an importer;

(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(ies) for which the license was granted, the country(ies) 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 to meet the needs of 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 no significant impact on the price; and (iii) prior to shipment, the licensee must post on a website (which may be a WTO website) the quantities being supplied to each destination and the distinguishing features of the product.

Partial waiver of the adequate remuneration requirement

Paragraph (h) of Article 31 of the TRIPS Agreement provides that “the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization.”

In order to avoid double compensation, this obligation is waived in the importing country provided that adequate remuneration was paid in the exporting country. The Decision specifies that the remuneration to be paid to the right 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.” No clarification was provided on the application of this standard.

¹⁸ The WTO refers to the United Nations’ designation of least-developed countries. The list is available at http://www.wto.org/english/thewto_e/whatis_e/tif_e/org7_e.htm.

Supplemental provisions of note

While the above-described mechanism constitutes the essence of the Decision, certain supplemental provisions and requirements must be noted:

The Decision covers not only patented products (and products manufactured through a patented process) of the pharmaceutical sector, 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 that are the subject of trade diversion.

Re-exportation is, however, permitted in the case of certain intra-regional trade agreement (“RTA”) transactions. When certain conditions are satisfied, paragraph 6 of the Decision waives Article 31(f) to allow the re-exportation of pharmaceutical products imported under a compulsory license to other developing or least-developed members of the RTA that experience the same public health problem. The conditions are that: (a) the RTA must be sanctioned by the WTO;¹⁹ and (b) at least half of the Members must be least-developed countries listed as such by the United Nations on the date of the Decision.²⁰

In practical application, this provision is of benefit to trade groupings in Africa. It allows them to make use of economies of scale by bulk procurement by one (or more) of the members, and it facilitates the importation of component materials, formulation into finished products, and export to countries of the RTA. In the event of re-exportation to members of the RTA, paragraph 6 of the Decision does not impose any obligation of notification to the WTO. As an additional flexibility, the regional organization may make the required notification to the WTO of actual importation on behalf of all the importing members of the RTA.²¹

For the avoidance of doubt, paragraph 6 clarifies that this waiver for RTAs is not intended to “prejudice the territorial nature of the patent rights in question.” This means that there still needs to be a voluntary or compulsory license in the importing Members of the RTA if the product is under patent there (unless the importing member is a least-developed country electing not to enforce relevant patents).

More generally, the Decision also contains provisions encouraging the development of

¹⁹ Meaning “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 on Developing Countries” (Paragraph 6 Decision, para. 6(i)).

²⁰ The actual text says “... countries presently on the United Nations list of least-developed countries ...” (Paragraph 6 Decision, para. 6(i)) (emphasis added)

²¹ Decision, note 4.

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. Negotiation of a formal amendment of the TRIPS Agreement based “where appropriate” on the Decision was to be started by the Council for TRIPS by December 31, 2003.²²

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 for the product(s) in question.

Finally, it is important to note that the Decision was issued with an accompanying statement of the Chairperson of the General Council. That statement purports to represent key understandings of the member countries with respect to the Decision and the way in which the Decision is to be interpreted and implemented. These understandings deal with essentially four things:

- the need for Members to implement the Decision in good faith to protect public health and not to pursue industrial or commercial policy objectives;²³
- guidelines to avoid trade diversion;
- ways in which the WTO Members will be informed about the operation of the system and ways in which issues can be raised and resolved; and
- the countries that have agreed entirely to opt out of the System as importers or that will apply the system to import only in situations of national emergency or other circumstances of extreme urgency.

The legal significance of the Chairperson’s statement is unclear. However, as a practical matter, countries seeking to avail themselves of the System would be well-advised to make sure that their implementation of the System is consistent with the statement. This should not add any significant burden.

²² A start was made, but progress has been slow.

²³ While the need to implement the Decision in good faith to protect public health is clear enough, the admonition to Members not to use the Decision to pursue industrial or commercial policy objectives is, under the circumstances, less so. To impose as a consequence, for example, price caps on exported generic products as was done in the Canadian legislation (*supra* n. 9) appears questionable : The issue should not be whether “the agreement is commercial in nature” (Bill C-9, Section 2.17(1))— the Decision relies on private commercial enterprises to produce and sell generics for export through commercial arrangements— but whether the **exporting country** uses the Decision to further its own national industrial or commercial policy objectives.

PART 2: MODEL LEGAL DOCUMENTS

This Part consists of six model legal documents to assist countries in implementing the Decision. Countries will need to adapt them to their own circumstances, but every effort has been made to provide, through these model documents, a convenient starting point for implementation of the Paragraph 6 Decision in a manner that is consistent with the letter and the spirit of the Decision and the Doha Declaration.

Documents 1, 2 and 3 are model notifications to the World Trade Organization required by the System. Document 4 is a model notification that is not required by the terms of the Paragraph 6 Decision but that is mandatory under Article 31 of the TRIPS Agreement; it is included here to ensure that this obligation is not overlooked. Alternative clauses are provided to reflect possible choices or different situations.

Documents 5 and 6 provide model provisions for the legislative or regulatory amendments that may be required in, respectively, the exporting country and the importing country.

It is important to note that Documents 5 and 6 are not intended as a substitute for complete national government use and compulsory licensing legislation or regulation. For WTO Members, Article 31 of the TRIPS Agreement generally establishes the conditions under which government use and compulsory licenses may be granted. Thus, for example, such licenses must be considered on their individual merits (Article 31(a)), must be non-exclusive (Article 31(d)), and they are subject to limitations on assignment (*i.e.*, they are non-assignable except with the part of the business or goodwill which enjoys use of the license). Article 31(l) establishes conditions with respect to the treatment of dependent patents. Article 31 also addresses review of compulsory licensing decisions. This Guide is limited to facilitating the implementation of the Paragraph 6 Decision -- further information on the requirements of Article 31 of the TRIPS Agreement is available from other sources.²⁴

Explanatory comments are provided in a separate section under each document.

The term “Member” in this text refers to member countries of the WTO.²⁵

²⁴ See *e.g.* UNCTAD/ICTSD, *Resource Book on TRIPS and Development: An Authoritative and Practical Guide to the TRIPS Agreement*, Part 2.5.8, available at <http://www.iprsonline.org>.

²⁵ The WTO has 148 members (WTO website, accessed January 12, 2005). The membership of the World Bank stands at 184 countries (January 12, 2005).

Document 1

Notification by Developing Country Member to Council for TRIPS of Intention to Use System as Importer

Notification to Council for TRIPS pursuant to General Council Decision of August 30, 2003 on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health

[Member name] hereby notifies the Council for TRIPS of its intention to use the system established by the August 30, 2003 Decision of the General Council on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, without limitation or restriction, as an importer.

This notification shall remain in force and effect unless and until modified or withdrawn by [Member].

Date of notification:

Commentary

Paragraph 1(b) of the Decision requires a one-time notification to the TRIPS Council of intention to use the system as an importer. However, least- developed country Members are automatically understood to be eligible importing Members and are not required to file a one-time notification.

The notification establishes a developing country Member as an “eligible importing Member.” The notifying Member has the option to indicate that it will use the system “in whole,” or in a “limited way.” By way of illustrating a “limited way,” an example is provided in the Decision of using the system “only in the case of a national emergency or other circumstance of extreme urgency or in cases of public non-commercial use.”

There is no a priori reason to self-impose a limitation on use of the system as an importer, and hence the draft notification contemplates notification of intent to use the System without restriction or limitation. The text of the Decision provides further that “a Member may notify **at any** time that it will use the system in whole or in a limited way.” (emphasis added)²⁶ This indicates flexibility to make subsequent modifications to the notification.²⁷

²⁶ Paragraph 6 Decision, para. 1(b).

²⁷ At the time of the Decision, a number of countries agreed not to make use of the System as importers (in whole or in part). Some others made statements to this effect in connection with the Chairperson’s statement. The flexibility noted in the text may not apply to these countries.

For importing Members that are not least-developed countries as recognized by the WTO,²⁸ a compulsory license authorizing importation will be required for products under patent in the importing Member. There may be limitations in national compulsory licensing law regarding the circumstances in which a license may be issued, such as a limitation framed along the lines of the examples set out in the Decision (emergencies, public non-commercial use, etc.). Limitations in national law may be different in respect to “government use” and third party licensing. There is no legal requirement to limit the notification to the TRIPS Council to those options that are presently open in national law. A notification of intention to use the system “in whole” from a Member with limited options in national law would be understood as subject to whatever limitations may exist under national law. It would not operate to eliminate restrictions under national law because the grant of a compulsory license for import under the system would still take place in accordance with the provisions of national law.

Footnote 2 to Paragraph 1(b) of the Decision provides that “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.” Therefore, a Member may transmit this notification to the TRIPS Council prior to discussion with or approval by any body at the WTO, including the TRIPS Council.

²⁸ See note 18 *supra*.

Document 2**Importation under the Paragraph 6 Decision:****Notification by Least-Developed Country Member**Notification of Importation under Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health***Paragraph 1:***

Based on its present evaluation of its public health needs, [Member] expects to import [quantity(ies)] of [pharmaceutical product name(s)]. However, because it is not possible to predict with certainty the extent of its public health needs, [Member] reserves the right to modify the foregoing estimate as necessary or appropriate.

Paragraph 2:

Alternative 1: There is no patent on [pharmaceutical product(s) name(s)] in {Member}. This notification is made because [pharmaceutical product(s) name(s)] is (are) under patent in the country of export.

Alternative 2: Pursuant to Paragraph 7 of the Doha Declaration and implementation thereof by the TRIPS Council (Decision of the Council for TRIPS of 27 June 2002), [Member] has decided that it will not enforce rights provided under Part II Section 5 of the TRIPS Agreement that may have been granted within its territory with respect to [pharmaceutical product name(s)].

Alternative 3: [Member] [intends to issue] [has issued] a license for the importation and distribution of [pharmaceutical product(s) name(s)] without the consent of the patent holder in accordance with the provisions of Article 31 of the TRIPS Agreement and the Decision. Pursuant to paragraph 3 of the Decision, remuneration to the patent holder shall be determined and paid in [country of export].

Date of notification:

Commentary***Paragraph 1:***

The Decision requires notification of the names and “expected” quantities of the pharmaceutical products needed. The objective of this provision is to discourage production and export of product that might be diverted to third country markets.

However, in many contexts – such as in HIV/AIDS treatment – it may be very difficult to provide concrete estimates of quantities needed over time, and the requirement of providing an estimate was presumably not intended to bind the exporting and importing Members to a set production amount. The objective of the System is to allow Members to satisfy their legitimate public health needs. For this reason, under the notification, it is recommended that a Member expressly reserve the right to revise the expected quantities to be imported.

The Decision does not establish any form or template for the notification of expected quantities. A Member might elect to indicate an aggregate “amount” of product to be imported over the duration of a license, or it might elect to indicate the amount it expects to import on a periodic basis (e.g., on an annual or quarterly basis). It may be appropriate to refer to “expected quantities” on a more subjective basis, such as “a quantity of pharmaceutical product ‘x’ sufficient to treat ‘y’ patients over ‘z’ period.” This might be a useful approach if, for example, there are different dosages and/or forms of administration of the product and the way in which orders for the product will be placed is not readily predictable.

Paragraph 2:

Three alternatives are provided to deal with three possible fact situations: (1) the pharmaceutical product in question is not under patent in the importing country; (2) as a WTO least-developed country Member, the country has decided to exercise its right not to enforce pharmaceutical patents; and (3) the importing country, in application of its patent law, will provide a compulsory license.

Alternative 1: This is straightforward and requires no explanation. It is of interest to note, though, that even if the pharmaceutical product in question is not under patent in the importing country, the notification of actual importation under the System is still required if the conditions to which the Decision applies pertain in the exporting country (i.e. the amount of product needed cannot be exported under the predominantly-for-the-domestic-market restriction in Article 31(b) of the TRIPS Agreement, or export of the product is not an exercise of an anti-competitive remedy under Article 31(k) of the TRIPS Agreement).

Alternative 2: This notifies of the intention not to enforce relevant patents. Pursuant to paragraph 7 of the Doha Declaration on the TRIPS Agreement and Public Health and implementing decisions by the TRIPS Council²⁹ and General Council,³⁰ least-developed country Members may elect not to enforce patents already granted with respect to pharmaceutical products and may choose not to grant product patents on pharmaceuticals until 2016.³¹ Footnote 6 to paragraph 2(a)(iii) of the Decision provides that the

²⁹ Decision of the Council for TRIPS of June 27, 2002.

³⁰ Decision of the General Council of July 8, 2002.

³¹ “We also agree that the least-developed country Members will not be obliged, with respect to pharmaceutical products, to implement or apply Sections 5 and 7 of Part II of the TRIPS Agreement or to enforce rights provided for under these Sections until 1 January 2016, without prejudice to the right of

requirement imposed on eligible importing Members to issue compulsory licenses with respect to pharmaceutical products under patent in their territory “is without prejudice to Article 66.1 of the TRIPS Agreement,” which is the specific provision under which the TRIPS Council authorized non-enforcement of patents by least- developed country Members.³² It is clear, then, that in using the system established by the Decision, a least-developed country Member may elect to authorize importation based on non-enforcement of relevant patents.

It is important to note that while the least-developed country Member can avoid international law liability under the TRIPS Agreement, it must also take the necessary steps to suspend the application of relevant patents under its national law. Patents are governed by domestic law and without appropriate legislative or regulatory action, the right holder could still bring an infringement claim in national court.

Alternative 3: This notifies of the intention to issue a compulsory license or that a compulsory license was issued. This fulfills the requirement set out in paragraph 2(a)(iii) of the Decision. Although not required, Alternative 3 is drafted to include reference to the fact that an obligation to pay remuneration in the importing country otherwise applicable pursuant to Article 31(h) of the TRIPS Agreement is waived by the Decision.

Alternative 3 does not state the grounds upon which a compulsory license has been, or may be, granted. A country may, but is not required to, state these grounds in its notification.

least-developed country Members to seek other extensions of the transition periods as provided for in Article 66.1 of the TRIPS Agreement. We instruct the Council for TRIPS to take the necessary action to give effect to this pursuant to Article 66.1 of the TRIPS Agreement.” (Doha Declaration on the TRIPS Agreement and Public Health, para. 7)

³² The decision of the Council for TRIPS of June 27, 2002 (*Extension of the transition period under Article 66.1 of the TRIPS Agreement for least-developed country Members for certain obligations with respect to pharmaceutical products*) provides in its operative provisions as follows: “(1) Least-developed country Members will not be obliged, with respect to pharmaceutical products, to implement or apply Sections 5 and 7 of Part II of the TRIPS Agreement or to enforce rights provided for under these Sections until 1 January 2016. (2) This decision is made without prejudice to the right of least-developed country Members to seek other extensions of the period provided for in paragraph 1 of Article 66 of the TRIPS Agreement.”

Document 3**Importation under the Paragraph 6 Decision:****Notification by Developing Country Member**Notification of Importation under Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health***Paragraph 1:***

Based on its present evaluation of its public health needs, [Member] expects to import [quantity(ies)] of [pharmaceutical product name(s)]. However, because it is not possible to predict with certainty the extent of its public health needs [Member] reserves the right to modify the foregoing estimate as necessary or appropriate.

Paragraph 2:

Alternative 1: There is no patent on [pharmaceutical product(s) name(s)] in [Member]. This notification is made because [pharmaceutical product(s) name(s)] is (are) under patent in the country of export.

Alternative 2: [Member] [intends to issue] [has issued] a license for the importation and distribution of [pharmaceutical product(s) name(s)] without the consent of the patent holder in accordance with the provisions of the TRIPS Agreement and the Decision. Pursuant to paragraph 3 of the Decision, remuneration to the patent holder shall be determined and paid in [country of export].

Paragraph 3:

Alternative 1: The Ministry [of ___] has examined data on the pharmaceutical sector available to it [and has consulted with experts in the pharmaceutical sector] and on that basis has determined that, excluding facilities owned or controlled by the patent holder(s), there is currently insufficient [no] capacity in the pharmaceutical sector for manufacture of the product(s) in question to meet the country's needs.

Alternative 2: The Ministry [of ___] has consulted with manufacturers in the pharmaceutical sector and has determined that, excluding facilities owned or controlled by the patent holder(s), there is currently insufficient [no] manufacturing capacity for the product(s) in question to meet the country's needs.

Alternative 3: [Member] confirms it has established that it has insufficient or no manufacturing capacities in the pharmaceutical sector for [pharmaceutical product(s)]. The methodology used to establish insufficient or no manufacturing capacities is

described in the attached Annex. [Attach a suitable document. It may be entitled Annex on Methodology of Determination of Insufficient or No Manufacturing Capacities for [pharmaceutical product(s)]]

Date of notification:

Commentary

Paragraph 1:

The Decision requires notification of the names and “expected” quantities of the pharmaceutical products needed. The objective of this provision is to discourage production and export of product that might be diverted to third country markets. However, in many contexts – such as in HIV/AIDS treatment – it may be very difficult to provide concrete estimates of quantities needed over time, and the requirement of providing the expected quantities was presumably not intended to bind the exporting and importing Members to a set production amount. The objective of the System is to allow Members to ratify their legitimate public health needs. For this reason, under the notification, it is recommended that a Member expressly reserve the right to revise the expected quantities to be imported.

The Decision does not establish any form or template for the notification of expected quantities. A Member might elect to indicate an aggregate “amount” of product to be imported over the duration of a license, or it might elect to indicate the amount it expects to import on a periodic basis (e.g., on an annual or quarterly basis). It may be appropriate to refer to “expected quantities” on a more subjective basis, such as “a quantity of pharmaceutical product ‘x’ sufficient to treat ‘y’ patients over ‘z’ period.” This might be a useful approach if, for example, there are different dosages and/or forms of administration of the product and the way in which orders for the product will be placed is not readily predictable.

Paragraph 2:

This paragraph deals with the requirement set out in paragraph 2(a)(iii) of the Decision.

Two alternatives are provided to deal with two possible fact situations: (1) the pharmaceutical product in question is not under patent in the importing country; and (2) the importing country, in application of its patent law, will provide a compulsory license.

Alternative 1: This is straightforward and requires no explanation. It is of interest to note, though, that even if the pharmaceutical product in question is not under patent in the importing country, the notification of actual importation under the System is still required if the conditions to which the Decision applies pertain in the exporting country (i.e. the

amount of product to be exported falls under the predominantly-for-the-domestic-market restriction in Article 31(b) of the TRIPS Agreement, and export of the product is not an exercise of an anticompetitive remedy under Article 31(k) of the TRIPS Agreement).

Alternative 2: This notifies of the intention to issue a compulsory license or that a compulsory license was issued. Although not required, Alternative 2 is drafted to include reference to the fact that an obligation to pay remuneration in the importing country otherwise applicable pursuant to Article 31(h) of the TRIPS Agreement is waived by the Decision.

Alternative 2 does not state the grounds upon which a compulsory license has or may be granted. A country may, but is not required to, state these grounds in its notification.

Paragraph 3:

Pursuant to paragraph 2 (a)(ii) of the Decision, an eligible importing Member that is not a least-developed country Member must establish that it has insufficient or no manufacturing capacities in the pharmaceutical sector with respect to the pharmaceutical product(s) in question according to criteria set out in Annex 1 to the Decision. Least-developed country Members are automatically deemed to have insufficient or no manufacturing capacities, so this requirement is effectively waived in respect to these countries.

Annex 1 provides in relevant part:

“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.”

The Chairperson’s statement issued in connection with the Decision further provides:

“To 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 capacity in the pharmaceutical sector.”

The Annex refers to the sufficiency of manufacturing capacities “for the product(s) in question.” Therefore, the Annex must be understood in the context of the specific pharmaceutical inventions for which production might be undertaken locally.

So, the first question that the Member should address is not whether there is general local manufacturing capacity in the pharmaceutical sector, but whether existing capacity (assuming there is some manufacturing capacity in the pharmaceutical sector) could be adapted without material expenditure to manufacture the pharmaceutical product(s) needed in a reasonable time to provide sufficient quantities meeting appropriate quality, safety, and efficacy standards. Alternatively, if there is some capacity to produce the pharmaceutical product in question, the question is whether that capacity is sufficient to manufacture the required quantities within a reasonable time and at appropriate quality, safety, and efficacy standards.

The information to be submitted in the notification process may be a brief statement regarding the methodology used by the Member in making a determination regarding insufficient or no manufacturing capacities.³³ This might be included directly in the body of the notification, as in Alternatives 1 and 2, or it might be incorporated in an Annex (Alternative 3).

While WTO Members have discretion in their evaluation of manufacturing capacity, it is prudent to bear in mind that a determination may be subject to review at a later stage.³⁴ Hence, it is important that such determination be undertaken in a way that can be reasonably substantiated.

³³ Following adoption of the Decision, the TRIPS Council delegate from India made the following statement regarding the reference in the Chairperson’s Statement to providing information regarding how insufficient manufacturing capacity is to be determined:

“It had been clarified during the consultations that this did not involve provision of a great deal of technical or other information, but only the brief and concise indication of the methodology for determination of insufficient or no manufacturing capacity and the conclusions that were drawn on the basis of available data.” General Council, Minutes of Meeting on 25, 26 and 30 August 2003, WT/GC/M/82, 17 Nov. 2003, at para. 52.

³⁴ The Council for TRIPS is required to review the functioning of the System annually. (Paragraph 6 Decision, para. 8) In addition, the Chairperson’s statement provides that: (i) all notifications must be brought to the attention of the TRIPS Council at its next meeting; (ii) any matter relating to the implementation of the Decision may be brought to the TRIPS Council by any Member for “expeditious review”; and (iii) the good offices of the Director General of the WTO or the Chair of the TRIPS Council may be enlisted to resolve concerns of any Member that the terms of the Decision have not been complied with. (Chairperson’s statement, “third”)

Document 4**Notification to Right Holder of Issuance of Compulsory License**Notification of Issuance of Compulsory License***Paragraph 1:***

Alternative 1: The [Register of Patents] held at [name and place of office of the governmental entity responsible for the grant and registration of patents] indicates that [name of patent or right holder] was issued Patent No(s) ... [or: rights to Patent No(s) ...] on [date].

This is to notify that [name of issuing authority] [intends to] [has granted] to [name of compulsory license holder] a license for the [exportation] [importation] of [pharmaceutical product(s) name(s)] without consent of the [patent] [right] holder to said [patent(s)] [right(s)] in accordance with the provisions of the Agreement on Trade-Related Aspects of Intellectual Property Rights, the World Trade Organization's Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health ("Decision"), and [reference to applicable domestic law].

Alternative 2: Notice is hereby given that the [issuing authority] [has authorized] [intends to authorize] [exportation] [importation] of [pharmaceutical product(s) name(s)] without the consent of any person(s) that may hold or control patent rights with respect to such product(s), in accordance with the provisions of the Agreement on Trade-Related Aspects of Intellectual Property Rights, the World Trade Organization's Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health ("Decision"), and [reference to applicable domestic law].

Paragraph 2:

Pursuant to paragraph 3 of the Decision, remuneration to the patent holder(s) shall be determined and paid in [country of export].

Date of notification:

Commentary

As noted before, the requirements of Article 31(b) of the TRIPS Agreement are not waived by the Decision. These requirements include that the right holder must be notified "as soon as reasonably practicable" when a compulsory license is granted in situations of "national emergency or other circumstances of extreme urgency." If the subject matter of a patent is used without the authorization of the patent or right holder in

a case of public non-commercial use where either the government or a government contractor “without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government,” then the right holder is to be informed “promptly.” Use of the phrase “without making a patent search” indicates that the government is under no obligation to investigate the patent status of a pharmaceutical product before issuing a government use license.

A compulsory license in favor of a third party or a government use license may cover all patents that apply to the subject matter. This approach is useful because a pharmaceutical product may be covered by a number of patents and it is sometimes difficult to determine what patents, if any, may be affected by a license as to a product.

Alternative 1 may be used in the situation in which the government authority issuing the license knows the particular patent(s) that will be affected by it.

Alternative 2 may be used in the situation in which the government authority issuing the license does not know what patent(s), if any, may cover the relevant product(s). Since the government does not know what person(s) may hold patents, it cannot notify that person(s) directly. Therefore, the notice might be given to the public, for example, in a government gazette.

While this notification is strictly speaking not part of the System, a model instrument has been included here in order to draw attention to the need to satisfy this requirement of Article 31(b) of the TRIPS Agreement. It may be noted that the obligation to provide such notification applies to both the exporting and the importing Member if they both have to issue a compulsory license under the System.

There is no template for this kind of notification and there are no pre-established requirements with regard to content. Members thus retain wide freedom. If the government is not the licensee, the Member does not even have to provide the notification or information itself; it may instruct the compulsory license holder to do the necessary.

Document 5**Patent Act Amendment for Exporting**Amendment to Patent Act

“For the purpose of giving effect to the Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, adopted by the World Trade Organization’s General Council on August 30, 2003, the [Patent Act] is amended by adding a new [Part ...] as follows:

[Part ...]

1. Definitions

(a) “Decision” means the Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, adopted by the World Trade Organization’s General Council on August 30, 2003;

(b) “Eligible Importing [Member] [Country]”

Alternative 1: (b) “Eligible Importing Member” means (i) any least-developed country Member of the World Trade Organization; and (ii) any Member of the World Trade Organization that has notified the Council for TRIPS of its intention to make use of the System (as hereinafter defined) as an importing country as prescribed by the Decision;

Alternative 2: (b) “Eligible Importing Country” means (i) any least-developed country Member of the World Trade Organization; (ii) any Member of the World Trade Organization that has notified the Council for TRIPS of its intention to make use of the System as an importing country as prescribed by the Decision; and (iii) any country which is not a member of the WTO but which represents by diplomatic representation to the Minister that it will follow the System and that it has posted on a public website the notifications required under paragraphs 1(b) and 2(a) of the Decision.

(c) “Minister” includes for purposes of this [Part...], and notwithstanding anything to the contrary in the [Patent Act], the [Minister of Health] who, for purposes of giving effect to this [Part], shall have authority under Section 2;

(d) “Pharmaceutical Product” has the meaning set out in paragraph 1(a) of the Decision.

(e) “System” means steps and/or measures prescribed by the Decision.

2. License

Subject to the provisions of Sections 3, 4, 5 and 6 of this [Part...] and [Sections ... of the Patent Act], on application of any person (hereinafter “Applicant”), the Minister may grant such person a license (hereinafter “the Licensee” and “the License,” respectively) to use the subject matter of a patent regarding [a] Pharmaceutical Product(s), including a patented process regarding [that][those] Pharmaceutical Product(s), without the consent of the patent holder, for purposes of making, using (including for domestic or foreign testing and regulatory approval), offering for sale for export, selling for export and exporting such Pharmaceutical Product(s) to an Eligible Importing [Member] [Country].

3. Application

(a) The application shall contain all information necessary to show, to the satisfaction of the Minister, that all requirements of this [Part ...] are, or will be, complied with.

(b) The application may [include] [be accompanied by] a representation from the Eligible Importing [Member] [Country] that the Pharmaceutical Product(s) is (are) needed to address a national emergency, other circumstances of extreme urgency, or for public non-commercial use. In such case, the application shall be treated as if such circumstance is present in [name of exporting Member] for purposes of the procedures to be followed in the granting of a license, including, *inter alia*, the waiver of any requirement for prior negotiation by the Applicant with the patent holder.

(c) If the application is submitted by, or on behalf of, an Eligible Importing [Member] [Country], the Minister [may] [shall] presume that the Pharmaceutical Product(s) subject of the application is (are) necessary to address the public health needs of that [Member] [Country]. When an application is not submitted by (or on behalf of) a governmental authority of an Eligible Importing [Member] [Country], if the Applicant submits evidence that the Eligible Importing [Member] [Country] supports the application (and the issuance by the Eligible Importing [Member] [Country] of a compulsory license in favor of the Applicant shall be conclusive evidence of such support), the Minister [may] [shall] presume that the Pharmaceutical Product(s) is (are) necessary to address the public health needs of the Eligible Importing [Member] [Country].

(d) If the eligible importing Member is not a least-developed country Member of the World Trade Organization, the application shall be accompanied by a copy of the notification of such eligible importing Member to the World Trade Organization of its intention to make use of the System as an importer.

4. Conditions

The License shall contain the following conditions:

(a) The quantity of Pharmaceutical Product(s) made under the license shall be limited to that necessary to address the needs of the Eligible Importing [Member] [Country], including production undertaken for purposes of testing and regulatory approval. Exports of Pharmaceutical Product(s) made under the License shall be limited to the Eligible

Importing [Member] [Country] and countries where testing and regulatory approval is sought.

(b) All Pharmaceutical Products exported under the license shall be clearly identified as produced under the System through specific labeling or marking. The exported Pharmaceutical Product(s) should be distinguished through special packaging and/or special coloring/shaping of the products themselves, provided that such distinction is feasible and does not have a significant impact on price.

(c) The Licensee shall, prior to shipment of the Pharmaceutical Product(s) to be exported, post on its website or on a website established for the purpose by the World Trade Organization:

- (i) The quantities of Pharmaceutical Product(s) to be supplied to each destination; and
- (ii) The distinguishing features as required under sub-Section 4(b) above.

5. Notification to the Council for TRIPS

The Minister shall notify the Council for TRIPS, or shall cause the Council for TRIPS to be notified through appropriate channels, of any license issued under Section 2. Such notification shall include:

- (a) The name and address of the licensee;
- (b) The Pharmaceutical Product(s) for which the License has been granted;
- (c) The quantity(ies) for which the License has been granted;
- (d) The country(ies) to which the Pharmaceutical Product(s) is (are) to be exported;
- (e) The duration of the license;
- (f) The address of the website on which the licensee will post information required by the Decision;
- (g) Any other conditions attached to the License[; and
- (h) The public website referred to in subsection 1(b)(iii)].

6. Remuneration

In determining remuneration to the patent holder under Section [...] of the [Patent Act] with respect to any license granted under Section 2, the Minister shall take into account the economic value of the authorization to the Eligible Importing [Member] [Country].

7. Marketing Approval

Notwithstanding anything to the contrary in [the national law(s) regarding the protection of data submitted for regulatory purposes], registration or marketing approval for Pharmaceutical Products covered by a License shall not be prevented, hindered, or delayed by claims of rights in data or for marketing exclusivity based on the patent holder's submission of regulatory data (confidential or otherwise) in [Member] or in another territory. This provision is without prejudice to requirements of the [national

regulatory authority] with respect to assessment of the quality, safety, and efficacy of the Pharmaceutical Product(s).

8. *Administrative Review*

Power to review and to terminate the License shall be vested in the Minister. There shall be no right of judicial review of the continued existence of the License unless the Minister has first issued a decision upon a motivated request for termination of the License.

Commentary

Introductory Note

Provided the System is followed, the Decision waives the requirement of Article 31(f) of the TRIPS Agreement that a compulsory license shall be issued predominantly for supply of the domestic market of the Member granting the license. Model Document 5 sets out a number of provisions that may be used to implement the waiver of the export restriction in existing government use and compulsory licensing legislation.

Most patent legislation distinguishes between authorization of government use of patents, on one hand, and authorization of third party (private sector) use of patents, on the other. Government use licensing is typically facilitated. In the discussion that follows, the terms “government use” and “compulsory licensing” (i.e., third party) are sometimes used to indicate that these types of authorizations are typically addressed in separate legislative provisions (which may well include cross-referencing to common rules); otherwise, the terms “License” or “license granted under Section 2” are used to denote both government use authorizations and compulsory licenses.

The same WTO Member may be both an exporting Member and an eligible importing Member under the Decision. Members may therefore wish to consider the amendments discussed in this Document 5 (for exporting) and the following Document 6 (for importing).

There are two main approaches to addressing implementation of the Paragraph 6 Decision. One approach is to adopt a legislative provision that provides for the promulgation of regulations concerning the operation of the System. A second approach is to reflect all necessary provisions for implementation of the Decision in a legislative provision (which in most, if not all, cases would be an amendment of the Patent Act) – this is the approach that has been taken in this Guide.

A regulatory approach has the advantage of greater flexibility. The terms of the Decision (taking the form of waivers) might be varied in the course of negotiations in the WTO of

a follow-on amendment to the TRIPS Agreement.³⁵ A regulatory approach should facilitate any adaptation that might be required as a result. Also, Members may wish to vary their approach to authorizations for export as experience is gained with using the System, and a regulatory approach again may facilitate adaptation.

In the event a regulatory approach is followed, a simple amendment of the Patent Act could be phrased as follows:

“Where exploitation of an invention relating to a product of the pharmaceutical sector without the consent of the patent holder is sought for the purpose of exports in implementation of the Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, the Minister shall follow the procedures set forth by regulation for the implementation of such Decision.”

With the basic authorizing legislation thus in place, implementing regulations might follow the provisions of Model Document 5.

Definitions

The Minister

Some patent statutes accord the power to grant government use or compulsory licenses to the Minister responsible for oversight of the patent office.³⁶ Particularly in situations where public health interests are at stake, it may be wise for Members to extend the power to authorize government use or compulsory licenses to additional Ministers, such as the Minister responsible for the public health system.

For example, it may be noted that under the British Crown Use authorization in its Patents Act “any government department and any person authorised in writing by a government department” may make use of a patent, including a patent concerning a drug or medicine, “without the consent of the proprietor of the patent” (Section 55 (1), U.K. Patents Act).

The legislation and regulations of each Member are different and it will therefore be necessary to adjust the draft provision to take into account the existing structure of the patent law. The specific way “Minister” is defined in the Model Document may need to be modified within the framework of existing law, but should nevertheless provide a

³⁵ Paragraph 11 of the Decision provides, in relevant part: “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 ...”. Progress on the preparation of the amendment has been slow.

³⁶ This is by no means a universal practice. For example, the U.S. statute authorizing government use of patents permits any federal agency or contractor to use patents without authorization from the patent office or the patent holder. *See also* the U.K. Patents Act Crown Use provision referred to in the text below.

reminder that inclusion of the Minister of Health as one of the officials authorized to make decisions in this area is important.³⁷

The authority of the Minister should include the power to review and to terminate the compulsory license upon a duly motivated request by the patent or right holder. This is provided in Section 8 of the Model Document.

Article 31(g) of the TRIPS Agreement provides that a license issued under Article 31 is liable to termination upon motivated request if and when the circumstances that led to the granting of the license have ceased to exist and are unlikely to recur. Any such termination would have to be subject to adequate protection of the legitimate interests of the licensee.

Judicial review is made more efficient by including a clause in the legislation, as provided in the Model Document (Section 8), that requires a prior ruling by the Minister (particularly if this term includes the Minister of Health, as recommended in the Model Document) on any request or petition for termination of the compulsory license. The Minister of Health is the proper government official to make a determination regarding the continued existence or not of the public health need that gave rise to the license. Any record developed by the Minister in this determination would be of material aid in a later judicial review. Also, a requirement of prior determination by the Minister forestalls premature filings of legal actions and assures that the supply of pharmaceutical products can continue without interruption while the request for termination of the license is reviewed.

Eligible Importing Members or Countries

As noted before, least developed-country Members of the WTO are automatically eligible to import under the System, and developing country Members are eligible if they have insufficient or no capacity with respect to the pharmaceutical products in question. However, it is foreseeable that countries that are not WTO Members will want to import pharmaceutical products under the System.

The first two industrialized countries that implemented the Decision in national law, Canada and Norway, made provision for use of the System by non-WTO Members.³⁸

³⁷ While Article 27.1 of the TRIPS Agreement provides that “patents shall be available and patent rights enjoyable without discrimination as to ... the field of technology”, authorizing the Minister of Health to grant government use or compulsory licenses for pharmaceutical products in implementation of the Decision should not be objectionable. The WTO panel in the *Canada – Patent Protection of Pharmaceutical Products* case made it clear that Members may adopt measures that distinguish among patents as to different types of products for good faith reasons, observing that “discrimination” as used in Article 27.1 “is a normative term, pejorative in connotation, referring to results of the unjustified imposition of differentially disadvantageous treatment.” It should be clear that authorizing the Minister of Health to make licensing determinations as to pharmaceutical products required to meet public health needs involves a *bona fide* distinction between authorizations regarding pharmaceutical products and authorizations regarding other types of products, such as, for example, those used in automobile engines.

³⁸ See generally n. 9 *supra*.

Hence, Alternative 2 provides a suitable definition if an exporting country wishes to use the System to allow exports to non-WTO member countries. As did Canada and Norway, Alternative 2 provides for diplomatic assurances from the importing non-WTO Member country that it will follow the measures laid out in the Decision.

Pharmaceutical Product

The definition of pharmaceutical product in Model Document 5 adopts the definition given in the Decision.³⁹

Paragraph 1(a) of the Decision gives the following definition of pharmaceutical product:

“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 included.”

This definition refers to “the public health problems as recognized in paragraph 1 of the Declaration.” That paragraph of the Declaration states in its entirety as follows:

“We [the Doha Ministerial Conference] recognize 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.”

The definition of pharmaceutical product in the Decision is the result of nearly two years of negotiations, and so it is not surprising that it is less than a straightforward statement. While the formulation is convoluted, it also is flexible. The exact scope of “pharmaceutical sector” may perhaps lead to questions in particular cases, but it is clear that the products covered encompass health products other than medicines, and so, for example, vaccines would appear to be included. In terms of the scope of diseases to be addressed by these products, the gravity of the public health problems of developing and least-developed country Members that the Ministers recognized are the result of a wide variety of diseases, including, but not limited to, the scourges of HIV/AIDS, tuberculosis, malaria, and other epidemics.

While Members must apply the Decision in good faith,⁴⁰ the Doha Declaration evidences strong recognition and acceptance by all WTO Members of the urgent need of developing

³⁹ This is also the approach adopted by Norway. The European Commission proposal and the Dutch rules refer broadly to pharmaceutical products for developing countries affected by public health problems, while the Canadian legislation uses a more restrictive approach. *See* note 9 *supra* for references to the country texts.

⁴⁰ The General Council Chairperson’s statement, second paragraph (“First, Members recognize that the system that will be established by the Decision 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.”)

and least-developed country Members to deal with their public health problems and, to that end, expressly reaffirms the right of Members to use all flexibilities in the TRIPS Agreement to the full.⁴¹ The definition of pharmaceutical product is, therefore, unlikely to be given a restrictive interpretation in practice, and it should not lead to significant problems in the implementation of the Decision.⁴²

In granting a compulsory license for the manufacture and export of a pharmaceutical product, it is important to consider that the product may be covered by a number of patents and it may be difficult for the applicant (including the government) to identify all potentially relevant patents. The authority responsible for granting the license may therefore formulate the grant so as to allow use by the applicant of all patents with respect to the identified product(s). Adequate compensation to the patent holder should take into account all patents that relate to the product(s).

The Application

National Emergency, Other Circumstances of Extreme Urgency and Public Non-Commercial Use

It is vitally important to recognize that Article 31(b) of the TRIPS Agreement establishes two distinct procedural regimes for the grant of compulsory licenses. In the ordinary commercial case, the applicant for a compulsory license must first have sought a voluntary license from the patent holder on reasonable commercial terms and conditions, and negotiations should not have succeeded within a reasonable period of time. The second regime applies to national emergencies, other circumstances of extreme urgency, and in cases of public non-commercial use. In these latter circumstances, prior negotiation with the patent holder may be waived and notification to the patent holder may follow the grant of a license. This is sometimes referred to as the “fast-track” option under Article 31(b).

Assume that an eligible importing Member is seeking supplies of products to treat HIV/AIDS. Paragraph 5(c) of the Doha Declaration expressly acknowledges that HIV/AIDS can constitute a national emergency or circumstance of extreme urgency. If an eligible importing Member requests exports of HIV/AIDS-related pharmaceutical products, the exporting country ought to be able to rely on a representation in the

⁴¹ In this connection, it may be recalled that the principal substantive provision of the Doha Declaration provides as follows: “ We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be 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 connection, we reaffirm the right of WTO Members to use, to the full, the provisions of the TRIPS Agreement, which provide flexibility for this purpose.” (Paragraph 4)

⁴² Useful further discussion of this topic may be found in Paul Vandoren and Jean Charles Van Eeckhoutte, *The WTO Decision on Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: Making it Work*, 6 J. World Intellectual Property 799, 784-85 (Nov. 2003) [and Frederick M. Abbott, *The WTO Medicines Decision: The Political Economy of World Pharmaceutical Trade and the Protection of Public Health*, 99 American J. of International Law (2005 forthcoming)].

compulsory license issued by the eligible importing Member that a national emergency or a circumstance of extreme urgency applies in that country with respect to HIV/AIDS and the Minister in the exporting country would therefore be justified in waiving the precondition of prior negotiation with the patent holder.

Facilitating the Approval Process

The Decision is intended to allow countries with insufficient or no relevant manufacturing capacity to make effective use of compulsory licensing. Ordinarily authorities within a country making a determination whether to grant a license do so based on conditions within their territory. The situation will be different in respect to applications from eligible importing Members under the Decision. The determination in the exporting country will be based on the situation in the importing country, which is where the public health problem exists. Absent exceptional circumstances, the Minister in the exporting Member should accept the determination by the eligible importing Member that its public health problems are such as to warrant use of the System and that they require importation of the pharmaceutical product(s) in question. This gives effect to the intent of the Decision, which is to allow least-developed countries Members and developing country Members without (or with insufficient) relevant manufacturing capacity to make effective use of compulsory licensing under the TRIPS Agreement.

Not all compulsory license applications will be made by governmental authorities. It is entirely possible that private enterprises, intergovernmental organizations and NGOs will seek to procure the export of pharmaceutical products under compulsory license. In these circumstances, the question arises as to how the Minister in the exporting country should evaluate whether the authorities in the eligible importing Member support the application within the framework of the Decision. It would appear that if the authorities in the eligible importing Member have issued a compulsory license in favor of an applicant, the Minister in the exporting country should be able to rely on the grant of that license as sufficient evidence that the eligible importing Member supports the application. If such a compulsory license has not yet been granted, or need not be granted because (a) the product is not under patent in the importing country or (b) the importing country is a WTO least-developed country Member and has decided not to enforce a relevant patent, the Minister in the exporting country should be able to rely on some other evidence furnished by the eligible importing Member that it supports the application. This might, by way of illustration, be in the form of a letter from the Ministry of Health.

Conditions

Product Quantity and Destination

Paragraph 2(b)(i) of the Decision limits production quantities and the destination of exports to the eligible importing Member(s) for which authorization is granted. Sub-Section 4(a) of the draft statute addresses this limitation. However, it also makes provision for testing and regulatory approval within and outside the exporting Member (which in any event may be deemed permitted under Article 30 of the TRIPS Agreement)

because testing laboratories and regulatory approval bodies may be located within or outside the exporting Member and the eligible importing Member(s). In establishing the quality, safety, and efficacy of a medicine, a manufacturer under compulsory license may wish to submit its product for regulatory approval outside the country of manufacture or destination of export because regulatory authorities in either the exporting or importing country(ies) may base their own regulatory approvals on determinations made in third countries.

Labeling and Other Identification

Paragraph 2(b)(ii) of the Decision imposes labeling or marking requirements so that products produced and exported under the System may be identified as such. The Chairperson's statement adopted in connection with the Decision also addresses the issue of identification, including a clarification that active ingredients as well as finished products must be identified. Regarding active ingredients, it was understood that a label placed on a container would constitute adequate identification.⁴³

The Decision and Chairperson's statement provide that additional special identification (such as packaging, coloring or shaping) should not be required if it would have a significant impact on price, although the Chairperson's statement suggests that this would not in general be the case. This will involve a case-by-case determination.

Remuneration

Paragraph 3 of the Decision indicates that adequate remuneration to the patent holder pursuant to Article 31(h) of the TRIPS Agreement shall be paid in the exporting Member, and waived in the importing Member. For the exporting Member, adequate remuneration should be determined "taking into account the economic value to the importing Member of the use that has been authorized in the exporting Member." The model text repeats the language of paragraph 3 of the Decision.

Although the Decision and Chairperson's statement do not provide specific guidance on how this standard is to be applied, negotiations on the Decision at the WTO were undertaken pursuant to the Doha Declaration. The Declaration emphasizes that the TRIPS Agreement should be interpreted and implemented in a manner supportive of access to medicines for all. Hence, market conditions and ability to pay in the eligible importing Member should be significant factors in determining the level of remuneration in the exporting Member.⁴⁴

⁴³ This was clarified during a consultation held among WTO delegations prior to adoption of the Decision by the General Council, and is reflected in the minutes of the August 30, 2003 General Council meeting in a statement by the Indian delegation ("With regard to packaging of active ingredients, it had been clarified to India that special labeling including indication of the destination country would meet the requirements", Minutes of Meeting of General Council of August 30, 2003, WT/GC/M/82, para. 52, Nov. 13, 2003).

⁴⁴ The Canadian law to implement the Paragraph 6 Decision provides that royalties will be determined in the manner to be set out in regulations and that the regulations will take into account "the humanitarian and non-commercial reasons" underlying the issuance of the compulsory license. (Bill C-9, *supra* n.9, Section 21.08(2)).

Marketing Approval

Most or all countries require that a pharmaceutical product be registered and/or granted marketing approval prior to internal distribution for prescription or use. The procedures for registration and/or marketing approval vary widely, ranging from payment of a prescribed fee for registration to rigorous scientific analysis of the proposed product and dosage form. Countries without substantial pharmaceutical research infrastructure may rely on the approval procedures undertaken by foreign authorities with recognized competence in the field of pharmaceutical analysis. Recently the World Health Organization has initiated a pre-qualification program that evaluates manufacturers to determine whether the products they produce meet appropriate quality assurance standards.⁴⁵

Since WTO Members follow different approaches to the registration and marketing approval of medicines, each exporting Member will need to determine whether and how the manufacturer of products for export under the Decision will be regulated in the sense of registration and quality control. Since products will be produced at the request of importers, one approach would be to rely on the pharmaceutical authorities in the importing Member for registration and testing. Alternatively, authorities in the exporting Member might require a demonstration of bio-equivalence with previously approved products, and compliance with in-country quality assurance standards. Or, the exporting and importing Member could each rely on the WHO pre-qualification procedure to inform their regulatory approval process.

Article 39.3 of the TRIPS Agreement requires Members to protect confidential regulatory submissions with respect to pharmaceutical products that utilize new chemical entities from disclosure and “unfair commercial use.” There is considerable debate among WTO Members regarding the nature of that obligation.⁴⁶

When a Member issues a compulsory license for export under the Decision, the government of the exporting Member will have made a determination that the needs of the eligible importing Member for the relevant medicine should be met. Under such circumstances, it would be inconsistent with the object and purpose of the Decision and the Doha Declaration to permit the originator company to block the implementation of

⁴⁵ Available at <http://mednet3.who.int/prequal>

⁴⁶ Certain WTO Members are of the view that Article 39.3 mandates the imposition of a period of market exclusivity in favor of the company that first submitted the data. This period is five years from the date of marketing approval in the United States and generally ten years in the European Union. *See generally* United States Trade Representative, *2004 Special 301 Report* at 4 (available at <http://www.ustr.gov/reports/2004-301/special310.htm>), citing also the rules in the European Union and other countries. However, while the United States has recently negotiated a number of free trade agreements that contain intellectual property rights chapters with data protection and market exclusivity rules, in the context of agreements with non-industrialized countries that contain such provisions, it has signed side letters or similar instruments stating that the intellectual property chapter of these agreements does not prevent “the effective implementation” of the Decision. (*See* the side letters on the free trade agreements with Bahrain and Morocco and the “Understanding Regarding Certain Public Health Measures” with the signatories of the Central America Free Trade Agreement, available at www.ustr.gov.)..

the license by an independent claim that the licensee should not obtain registration or marketing approval of the product because the patent holder has previously submitted data to a regulatory authority. This would defeat the purpose of granting the compulsory license to export.

Document 6**Patent Act Amendment for Importing**Amendment to Patent Act

“For the purpose of giving effect to the Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, adopted by the World Trade Organization’s General Council on August 30, 2003, the [Patent Act] is amended by adding a new [Part ...] as follows:

[Part...]

1. Definitions

- (a) “Decision” means the Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, adopted by the World Trade Organization’s General Council on August 30, 2003;
- (b) “Minister” includes for purposes of this [Part...], and notwithstanding anything to the contrary in the [Patent Act], the [Minister of Health] who, for purposes of giving effect to this [provision], shall have authority to authorize importation under Section 2.
- (c) “Pharmaceutical Product” has the meaning set out in paragraph 1(a) of the Decision.
- (d) “System” means steps and/or measures prescribed by the Decision;
- (e) “Member” means a member of the World Trade Organization.

2. License

- (a) Subject to [the provisions of Sections 3 and 4 of this [Part ...] and] [Sections ... of the Patent Act], on application of any person (hereinafter “Applicant”) for authorization for the importation of a Pharmaceutical Product(s) that is (are) under patent(s) within [name of Member] and which is (are) also under patent(s) in a prospective exporting Member, the Minister may grant such person a license (hereinafter “the Licensee” and “the License,” respectively) for the importation of such Pharmaceutical Product(s) without the consent of the patent holder(s) in [name of Member] from the exporting Member pursuant to an authorization to be granted by the exporting Member.
- (b) The License shall include the name(s) of the Pharmaceutical Product(s) in question and an estimate of the quantities of the Pharmaceutical Product(s) to be imported during the term of the License; provided, however, that such estimate

shall not constitute a limitation on the quantities of the Pharmaceutical Product needed in [name of Member] to address the public health problem that the Pharmaceutical Product(s) is (are) intended to address.

(c) The Minister may determine that: (i) there exists within the nation a situation of national emergency or extreme urgency with respect to the public health problem the requested imports are intended to address; or (ii) the requested imports are intended for a public non-commercial use within [name of Member]. Notwithstanding anything to the contrary in [the existing Patent Act procedures for the grant of a compulsory license], if the Minister makes such determination, any requirement for prior negotiation by the Applicant with the patent holder for a license shall be waived. In this case, the Minister shall note this fact in the body of the license so that it may be relied upon by authorities in the exporting Member.

3. *Conditions [THIS SECTION ONLY TO BE USED BY ELIGIBLE IMPORTING MEMBERS THAT ARE NOT LEAST-DEVELOPED COUNTRY MEMBERS]*

No License shall be granted under sub-Section 2(a) of this [Part...] unless:

(a) the Minister has made a prior determination that there is insufficient or no manufacturing capacity with respect to the Pharmaceutical Product(s) in question in accordance with one of the ways set out in the Annex to the Decision; and

(b) The Minister, or other appropriate authority of [name of Member], has notified the World Trade Organization's Council for TRIPS of [name of Member]'s intention to use the System as an importer.

4. *Notification of the World Trade Organization*

Alternative 1: [The Eligible Importing Member is not a least-developed country Member and the Pharmaceutical Product is under patent in its territory]

Prior to the commencement of importation under the License, the Minister [or other appropriate authority of the Member] shall notify the World Trade Organization's Council for TRIPS of :

(a) the grant, or intent to grant, of a [compulsory license] [government use license] in accordance with the provisions of the Decision and [relevant sections of domestic law that incorporate the provisions of Article 31 of the TRIPS Agreement];

(b) the name(s) of the Pharmaceutical Product(s) and the expected quantities to be imported under the License; and

(c) the determination regarding insufficient or no manufacturing capacity referred to in sub-Section 3(a) of this Part.

Alternative 2: [The Eligible Importing Member is a least-developed country Member and the Pharmaceutical Product is under patent in its territory]

Prior to the commencement of importation under the License, the Minister [or other appropriate authority of the Member] shall notify the World Trade Organization's Council for TRIPS of:

(a) the grant, or intent to grant, of a [compulsory license] [government use license] in accordance with the provisions of the Decision and [relevant sections of domestic law that incorporate the provisions of Article 31 of the TRIPS Agreement]; and

(b) the name(s) of the Pharmaceutical Product(s) and the expected quantities to be imported under the License.

5. *No Remuneration*

The License granted pursuant to sub-Section 2(a) of this Part is not subject to the payment of remuneration to the patent holder(s) within [Member] in respect of the Pharmaceutical Products for which remuneration is paid in the exporting Member in accordance with paragraph 3 of the Decision.

6. *Marketing Approval*

Notwithstanding anything to the contrary in [the national law(s) regarding the protection of data submitted for regulatory purposes], authorization for importation without the consent of the patent holder granted pursuant to this [Part] shall allow the importer to register and obtain marketing approval for the Pharmaceutical Product(s) from the [national regulatory authority] and shall allow the [national regulatory authority] to authorize marketing approval and registration of the subject Pharmaceutical Product(s). This provision is without prejudice to requirements of the [national regulatory authority] with respect to assessment of the quality, safety, and efficacy of the Pharmaceutical Product(s).

Commentary

Introductory Note

Under the TRIPS Agreement, least-developed country Members may elect not to enforce pharmaceutical patents at least until January 1, 2016.⁴⁷ Countries that make this election should take appropriate action under their domestic law (or regulations) in order to avoid the possibility of infringement suits being brought before its courts. Model Document 6 does not address this situation.

⁴⁷ See the comment on Document 2, paragraph 3, alternative 2 in the text, and accompanying notes.

Model Document 6 is provided for the guidance of least-developed country Members that do not make an election to forego enforcement of patents and for developing country Members. In the remainder of this Commentary, both are referred to as “importing Member.”

The patent statute of an importing Member should generally allow for importation under government use or compulsory license. In cases where the pharmaceutical products in question are not under patent in an exporting country, but are under patent in the importing country, the ordinary procedures for grant of a government use or compulsory license should be followed in the importing Member .

The System should only be used when it is necessary to request the issuance of a government use or compulsory license in an exporting Member because the needed pharmaceutical products are under patent in that country.⁴⁸

Definitions

The Minister

The comments provided on this topic for Model Document 5 are applicable here.

Pharmaceutical Product

The comments provided on this topic for Model Document 5 are applicable here. The reference to “manufacture and export” in the last paragraph of these comments must be understood to refer to “import.”

License

Product quantity

Sub-Section 2(b) of the Model Document stipulates that the compulsory license to be issued by the importing Member specify the estimated quantity of the pharmaceutical product to be imported. It may be difficult to estimate the total needs of the country, nor may it be desirable to source all necessary imports—which could span over a number of years—from the same supplier in the same exporting country. To avoid unnecessary rigidity, it would be useful to include in the legislative provision a recognition that the amount of product stated in the license is not necessarily the total amount of product needed in the importing country. The phrasing of sub-Section 2(b) is consistent with the

⁴⁸ It should be recalled that, if the exporting country has previously granted a government use or compulsory license predominantly for the supply of the domestic market and there is sufficient supply also to satisfy the requirements of the importing country (without that becoming the predominant supply under the license), the importing country does not need to use the System. In addition, if the exporting Member has granted a license to remedy an anti-competitive practice pursuant to Article 31(k) of the TRIPS Agreement, it need not apply the restriction on exports in Article 31(f).

corresponding provisions in the notifications to the WTO provided in model documents 2 and 3.

Waiver of prior notification requirement

Sub-section 2(c) of Model Document 6 authorizes the Minister to make a determination that a situation of national emergency or extreme urgency exists, or that the products are being requested for public non-commercial use. This will allow authorities in the exporting Member to waive the precondition of prior negotiation with the patent holder and thereby expedite supplies.

The option permitted under Article 31(b) of the TRIPS Agreement, to waive the requirement that an applicant for a compulsory license shall have first sought a voluntary license from the patent holder, should be reflected in the national patent law of the importing country. Sub-Section 2(c) of Model Document 6 enables this waiver notwithstanding the terms of the existing patent legislation. However, if this “fast track” option is not already part of the patent law of the importing country, an amendment to implement this option should be introduced in addition to the changes proposed in this Model Document because it may be important in situations not involving implementation of the Decision.

Notification of the World Trade Organization

The notification set forth in Section 4 of Model Document 6 is not part of the license but is included because the giving of this notification is a condition to TRIPS-compliant authorization of a license.⁴⁹ It is not strictly necessary to provide for this in the amendment of the Patent Act (as done in Model Document 6); the notification requirement might equally well be included in any relevant regulations.

Notification to the Council for TRIPS would ordinarily be made not by the Minister (as defined in Section 1(a) of Model Document 6) but by the government representative assigned to WTO matters, such as the Ambassador to the WTO or his/her designee.

Two alternative formulations of the notification requirement are offered in Model Document 6. They only differ in that least-developing country Members do not need to include any determination regarding insufficient or no manufacturing capacity.⁵⁰

An eligible importing Member that is not a least-developed country Member must establish that it has insufficient or no manufacturing capacity in the pharmaceutical sector with respect to the product(s) in question pursuant to criteria set out in Annex 1 to the Decision.

Annex 1 provides as follows:

⁴⁹ Decision, para. 2(a).

⁵⁰ Decision, para. 2(a)(ii).

“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:

the Member in question has established that it has no manufacturing capacity in the pharmaceutical sector;

OR

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.”

The Chairperson’s statement adopted in connection with the approval of the Decision further provided:

“To 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 capacity in the pharmaceutical sector.”

The Annex refers to the sufficiency of manufacturing capacities “for the product(s) in question.” Therefore, the Annex must be understood in the context of the specific pharmaceutical inventions for which production might be undertaken locally. The question that the subject Member should address is not whether there is general local manufacturing capacity used for pharmaceutical products but whether that existing capacity (assuming there is some capacity) could be adapted without material expenditure to manufacture the pharmaceutical product(s) needed in a reasonable time to provide sufficient quantities meeting appropriate quality, safety, and efficacy standards, or if there is some capacity to produce the pharmaceutical product in question, whether that capacity is sufficient to manufacture the required quantities within a reasonable time and at appropriate quality, safety, and efficacy standards.

The information to be submitted in the notification process may be a brief statement regarding the methodology used by the Member in making a determination regarding insufficient or no manufacturing capacities.⁵¹

⁵¹ Following adoption of the Decision, the TRIPS Council delegate from India made the following statement regarding Chairperson’s Statement reference to providing information regarding how insufficient manufacturing capacity is to be determined:

“It had been clarified during the consultations that this did not involve provision of a great deal of technical or other information, but only the brief and concise indication of the methodology for determination of insufficient or no manufacturing capacity and the conclusions that were drawn on the basis of available

While WTO Members have discretion in their evaluation of manufacturing capacity, it is prudent to bear in mind that such determination may be subject to review at a later stage. Hence, it is important that such determination be undertaken in a way that can be reasonably substantiated.

Marketing Approval

Most or all countries require that a pharmaceutical product be registered and/or granted marketing approval prior to internal distribution for use. The procedures for registration and/or marketing approval vary widely, ranging from payment of a prescribed fee for registration to rigorous scientific analysis of the proposed product and its intended use. Countries without substantial pharmaceutical research infrastructure may rely on the approval procedures undertaken by foreign authorities with recognized competence in the field of pharmaceutical analysis. The World Health Organization has initiated a pre-qualification program that evaluates manufacturers to determine whether the products they produce meet appropriate quality assurance standards.

Article 39.3 of the TRIPS Agreement requires Members to protect confidential regulatory submissions with respect to pharmaceutical products that utilize new chemical entities from disclosure and “unfair commercial use”. There is considerable debate among WTO Members regarding the nature of this obligation.⁵²

When a Member issues a compulsory license for import under the Decision, the government of the importing Member will have made a determination that its needs for the relevant pharmaceutical product should be met. Under such circumstances, it would be inconsistent with the object and purpose of the Decision and the Doha Declaration to permit the originator company to block the implementation of the license by an independent claim that the licensee should not obtain registration or marketing approval of the product because the patent holder has previously submitted data to a regulatory authority. This would defeat the purpose of granting the license to import. A rule that

data.” General Council, Minutes of Meeting on 25, 26 and 30 August 2003, para. 52, WT/GC/M/82, 17 Nov. 2003.

⁵² Certain WTO Members are of the view that Article 39.3 mandates the imposition of a period of market exclusivity in favor of the originator company that submitted the safety and efficacy data sought to be relied upon by the second company. This period is five years from the date of marketing approval in the United States and generally ten years in the European Union. *See generally* United States Trade Representative, *2004 Special 301 Report* at 4 (available at <http://www.ustr.gov/reports/2004-301/special310.htm>), citing also the rules in the European Union and other countries. However, it appears that an exemption is being carved out for the purpose of implementing the Decision. Even though the United States has recently negotiated a number of free trade agreements that contain intellectual property rights chapters with data protection and market exclusivity rules, in the context of agreements with non-industrialized countries that contain such provisions it has signed side letters or similar instruments stating that the intellectual property chapter of these agreements does not prevent “the effective implementation” of the Decision. *See* the side letters on the free trade agreements with Bahrain and Morocco and the “Understanding Regarding Certain Public Health Measures” with the signatories of the Central America Free Trade Agreement, available at www.ustr.gov.

claims in data may not impede the execution of the license is stated in Section 6 of the Model Document.

To be clear, Section 6 does not address the nature of the regulatory approval methodology the importing Member adopts in terms of the quality and safety of the relevant pharmaceutical product. Thus, for example, it does not address whether and how the importing Member may determine whether a pharmaceutical product is bioequivalent to an originator product.

APPENDIX I**Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health**

Decision of the General Council 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 (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;

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 included; ⁽¹⁾

(b) “eligible importing Member” means any least-developed country Member, and any other Member that has made a notification ⁽²⁾ 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 Members and that some other Members ⁽³⁾ 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 notification ⁽²⁾ to the Council for TRIPS, that:

- (i) specifies the names and expected quantities of the product(s) needed ⁽⁵⁾;
- (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
- (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 Decision ⁽⁶⁾;

(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 website ⁽⁷⁾ 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 notify ⁽⁸⁾ 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.

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.

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.

Notes:

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, Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland, United Kingdom and United States of America.
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.
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.

APPENDIX II

General Council Chairperson's Statement

Excerpt from the minutes of the General Council meeting 30 August 2003 (paragraph n°29)

The General Council has been presented with a draft Decision contained in document IP/C/W/405 to implement paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health. This Decision is part of the wider national and international action to address problems as recognized in paragraph 1 of the Declaration. Before adopting this Decision, I would like to place on the record this Statement which represents several key shared understandings of Members regarding the Decision to be taken and the way in which it will be interpreted and implemented. I would like to emphasize that this Statement is limited in its implications to paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health.

First, Members recognize that the system that will be established by the Decision 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.

Second, 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. In this regard, 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. It 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.

In the past, companies have developed procedures to prevent diversion of products that are, for example, provided through donor programmes. "Best practices" guidelines that draw upon the experiences of companies are attached to this statement for illustrative purposes. Members and producers are encouraged to draw from and use these practices, and to share information on their experiences in preventing diversion.

Third, it is important that Members seek to resolve any issues arising from the use and implementation of the Decision expeditiously and amicably:

- To 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.

- 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.

Fourth, all information gathered on the implementation of the Decision shall be brought to the attention of the TRIPS Council in its annual review as set out in paragraph 8 of the Decision.

In addition, as stated in footnote 3 to paragraph 1(b) of the Decision, 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.

Until their accession to the European Union, the Czech Republic, Cyprus, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, the Slovak Republic and Slovenia agree that they would only use the system as importers in situations of national emergency or other circumstances of extreme urgency. These countries further agree that upon their accession to the European Union, they will opt out of using the system as importers.

As we have heard today, and as the Secretariat has been informed in certain communications, some other Members have agreed that they would only use the system as importers in situations of national emergency or other circumstances of extreme urgency. These are the following: 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”.

Attachment

“Best practices” guidelines

Companies have often used special labelling, colouring, shaping, sizing, etc. to differentiate products supplied through donor or discounted pricing programmes from products supplied to other markets. Examples of such measures include the following:

- Bristol Myers Squibb used different markings/imprints on capsules supplied to sub Saharan Africa.

- Novartis has used different trademark names, one (Riamet®) for an anti-malarial drug provided to developed countries, the other (Coartem®) for the same products supplied to developing countries. Novartis further differentiated the products through distinctive packaging.
- GlaxoSmithKline (GSK) used different outer packaging for its HIV/AIDS medications Combivir, Epivir and Trizivir supplied to developing countries. GSK further differentiated the products by embossing the tablets with a different number than tablets supplied to developed countries, and plans to further differentiate the products by using different colours.
- Merck differentiated its HIV/AIDS antiretroviral medicine CRIVAN through special packaging and labelling, i.e., gold-ink printing on the capsule, dark green bottle cap and a bottle label with a light-green background.
- Pfizer used different colouring and shaping for Diflucan pills supplied to South Africa.

Producers have further minimized diversion by entering into contractual arrangements with importers/distributors to ensure delivery of products to the intended markets.

To help ensure use of the most effective anti-diversion measures, Members may share their experiences and practices in preventing diversion either informally or through the TRIPS Council. It would be beneficial for Members and industry to work together to further refine anti-diversion practices and enhance the sharing of information related to identifying, remedying or preventing specific occurrences of diversion.

APPENDIX IIIDeclaration on the TRIPS Agreement and Public Health

Adopted at Doha, Qatar, on 14 November 2001

1. We recognize 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.
2. We stress the need for the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) to be part of the wider national and international action to address these problems.
3. We recognize that intellectual property protection is important for the development of new medicines. We also recognize the concerns about its effects on prices.
4. We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the 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 connection, we reaffirm the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.

5. Accordingly and in the light of paragraph 4 above, while maintaining our commitments in the TRIPS Agreement, we recognize that these flexibilities include:
 - (a) In applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles.
 - (b) Each member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.
 - (c) Each member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.
 - (d) The effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each member free to establish its own regime for such exhaustion without challenge, subject to the MFN and national treatment provisions of Articles 3 and 4.

6. We recognize 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. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002.

7. We reaffirm the commitment of developed-country Members to provide incentives to their enterprises and institutions to promote and encourage technology transfer to least-developed country Members pursuant to Article 66.2. We also agree that the least-developed country Members will not be obliged, with respect to pharmaceutical products, to implement or apply Sections 5 and 7 of Part II of the TRIPS Agreement or to enforce rights provided for under these Sections until 1 January 2016, without prejudice to the right of least-developed country Members to seek other extensions of the transition periods as provided for in Article 66.1 of the TRIPS Agreement. We instruct the Council for TRIPS to take the necessary action to give effect to this pursuant to Article 66.1 of the TRIPS Agreement.

APPENDIX IVAgreement on Trade-Related Aspects of Intellectual Property Rights, Article 31(Other Use Without Authorization of the Right Holder)

Where the law of a Member allows for other use of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected:

- (a) authorization of such use shall be considered on its individual merits;
- (b) such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. This requirement may be waived by a Member in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. In situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonably practicable. In the case of public non-commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly;
- (c) the scope and duration of such use shall be limited to the purpose for which it was authorized, and in the case of semi-conductor technology shall only be for public non-commercial use or to remedy a practice determined after judicial or administrative process to be anti-competitive;
- (d) such use shall be non-exclusive;
- (e) such use shall be non-assignable, except with that part of the enterprise or goodwill which enjoys such use;
- (f) any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use;
- (g) authorization for such use shall be liable, subject to adequate protection of the legitimate interests of the persons so authorized, to be terminated if and when the circumstances which led to it cease to exist and are unlikely to recur. The competent authority shall have the authority to review, upon motivated request, the continued existence of these circumstances;

⁷ "Other use" refers to use other than that allowed under Article 30.

- (h) the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization;
- (i) the legal validity of any decision relating to the authorization of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;
- (j) any decision relating to the remuneration provided in respect of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;
- (k) Members are not obliged to apply the conditions set forth in subparagraphs (b) and (f) where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive. The need to correct anti-competitive practices may be taken into account in determining the amount of remuneration in such cases. Competent authorities shall have the authority to refuse termination of authorization if and when the conditions which led to such authorization are likely to recur;
- (l) where such use is authorized to permit the exploitation of a patent ("the second patent") which cannot be exploited without infringing another patent ("the first patent"), the following additional conditions shall apply:
 - (i) the invention claimed in the second patent shall involve an important technical advance of considerable economic significance in relation to the invention claimed in the first patent;
 - (ii) the owner of the first patent shall be entitled to a cross-licence on reasonable terms to use the invention claimed in the second patent; and
 - (iii) the use authorized in respect of the first patent shall be non-assignable except with the assignment of the second patent.

APPENDIX V

CANADAPatent Act and the Food and Drugs Act (The Jean Chrétien Pledge to Africa),
An Act to amend the PATENT ACT

R.S., c. P-4

PATENT ACT

1. The *Patent Act* is amended by adding the following after section 21:

USE OF PATENTS FOR
INTERNATIONAL
HUMANITARIAN PURPOSES
TO ADDRESS PUBLIC HEALTH
PROBLEMS

Purpose

21.01 The purpose of sections 21.02 to 21.2 is to give effect to Canada and Jean Chrétien's pledge to Africa by facilitating access to pharmaceutical products to address public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.

Definitions

21.02 The definitions in this section apply in this section and in sections 21.03 to 21.19.

"authorization"
« *autorisation* »

uthorization" means an authorization granted under subsection 21.04(1), and includes an authorization renewed under subsection 21.12(1).

L.R., ch. P-4

LOI SUR LES BREVETS

1. La *Loi sur les brevets* est modifiée par adjonction, après l'article 21, de ce qui suit :

USAGE DE BREVETS A DES
FINS HUMANITAIRES
INTERNATIONALES EN VUE
DE REMEDIER AUX
PROBLEMES DE SANTE
PUBLIQUE

Objet

21.01 Les articles 21.02 à 21.2 ont pour objet de donner effet à l'engagement du Canada et de Jean Chrétien envers l'Afrique en facilitant l'accès aux produits pharmaceutiques nécessaires pour remédier aux problèmes de santé publique touchant de nombreux pays en voie de développement et pays les moins avancés, en particulier ceux résultant du VIH/SIDA, de la tuberculose, du paludisme et d'autres épidémies.

Définitions

21.02 Les définitions qui suivent s'appliquent au présent article et aux articles 21.03 à 21.19.

« Accord sur les
ADPIC »
« *TRIPS*
Agreement »

Accord sur les ADPIC » L'Accord sur les aspects des droits de propriété intellectuelle qui touchent au commerce, figurant à l'annexe 1C de l'Accord

<p>“General Council” « <i>Conseil général</i> »</p>	<p>“General Council” means the General Council of the WTO established by paragraph 2 of Article IV of the Agreement Establishing the World Trade Organization, signed at Marrakesh on April 15, 1994.</p>	<p>instituant l’Organisation mondiale du commerce signé à Marrakech le 15 avril 1994.</p>	<p>« autorisation » “<i>authorization</i>”</p>
<p>“General Council Decision” « <i>décision du Conseil général</i> »</p>	<p>“General Council Decision” means the decision of the General Council of August 30, 2003 respecting Article 31 of the TRIPS Agreement, including the interpretation of that decision in the General Council Chairperson’s statement of that date.</p>	<p>Conseil des ADPIC » Le conseil visé dans l’Accord sur les ADPIC.</p>	<p>« Conseil des ADPIC » “<i>TRIPS Council</i>”</p>
<p>“patented product” « <i>produit breveté</i> »</p>	<p>“patented product” means a product the making, constructing, using or selling of which in Canada would infringe a patent in the absence of the consent of the patentee.</p>	<p>Conseil général » Le Conseil général de l’OMC créé par le paragraphe 2 de l’article IV de l’Accord instituant l’Organisation mondiale du commerce, signé à Marrakech le 15 avril 1994.</p>	<p>« Conseil général » “<i>General Council</i>”</p>
<p>“pharmaceutical product” « <i>produit pharmaceutique</i> »</p>	<p>“pharmaceutical product” means any patented product listed in Schedule 1 in, if applicable, the dosage form, the strength and the route of administration specified in that Schedule in relation to the product.</p>	<p>décision du Conseil général » La décision rendue le 30 août 2003 par le Conseil général à l’égard de l’article 31 de l’Accord sur les ADPIC, y compris l’interprétation donnée de celle-ci dans la déclaration de son président faite le même jour.</p>	<p>« décision du Conseil général » “<i>General Council Decision</i>”</p>
<p>“TRIPS Agreement” « <i>Accord sur les ADPIC</i> »</p>	<p>“TRIPS Agreement” means the Agreement on Trade-Related Aspects of Intellectual Property Rights, being Annex 1C of the Agreement Establishing the</p>	<p>OMC » L’Organisation mondiale du commerce constituée par l’article I de l’Accord instituant l’Organisation mondiale du commerce, signé à</p>	<p>« OMC » “<i>WTO</i>”</p>

<p>“TRIPS Council” « Conseil des ADPIC »</p>	<p>World Trade Organization, signed at Marrakesh on April 15, 1994.</p> <p>“TRIPS Council” means the council referred to in the TRIPS Agreement.</p>	<p>Marrakech le 15 avril 1994.</p> <p>produit breveté » Produit dont la fabrication, la construction, l’exploitation ou la vente au Canada sans le consentement du breveté constituerait une contrefaçon.</p>	<p>« produit breveté » » “patented product”</p>
<p>“WTO” « OMC »</p>	<p>WTO” means the World Trade Organization established by Article I of the Agreement Establishing the World Trade Organization, signed at Marrakesh on April 15, 1994.</p>	<p>produit pharmaceutique » Produit breveté figurant à l’annexe 1, dans la forme posologique et selon la concentration et la voie d’administration indiquées, le cas échéant.</p>	<p>« produit pharmaceutique » » “pharmaceutical product”</p>
<p>Amending Schedules</p>	<p>21.03 (1) The Governor in Council may, by order, (a) on the recommendation of the Minister and the Minister of Health, amend Schedule 1 (i) by adding the name of any patented product that may be used to address public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics and, if the Governor in Council considers it appropriate to do so, by adding one or more of the following in respect of the patented product, namely, a dosage form, a strength and a route of administration, and (ii) by removing any entry listed in it; (b) on the recommendation</p>	<p>21.03 (1) Le gouverneur en conseil peut, par décret : a) sur recommandation du ministre et du ministre de la Santé, modifier l’annexe 1 : (i) par adjonction du nom d’un produit breveté pouvant être utilisé pour remédier à des problèmes de santé publique touchant de nombreux pays en voie de développement et pays les moins avancés, en particulier ceux résultant du VIH/SIDA, de la tuberculose, du paludisme et d’autres épidémies, et de la mention de la forme posologique, de la concentration ou de la voie d’administration du produit, s’il le juge indiqué, (ii) par suppression du nom d’un produit breveté ou d’une mention y figurant; b) sur recommandation du</p>	<p>Modification des annexes</p>

of the Minister of Foreign Affairs, the Minister for International Trade and the Minister for International Cooperation, amend Schedule 2 by adding the name of any country recognized by the United Nations as being a least-developed country that has,

(i) if it is a WTO Member, provided the TRIPS Council with a notice in writing stating that the country intends to import, in accordance with the General Council Decision, pharmaceutical products, as defined in paragraph 1(a) of that decision, and

(ii) if it is not a WTO Member, provided the Government of Canada with a notice in writing through diplomatic channels stating that the country intends to import pharmaceutical products, as defined in paragraph 1(a) of the General Council Decision, that it agrees that those products will not be used for commercial purposes and that it undertakes to adopt the measures referred to in Article 4 of that decision;

(c) on the recommendation of the Minister of Foreign Affairs, the Minister for International Trade and the Minister for International Cooperation, amend Schedule 3 by adding the name of any WTO Member not listed in Schedule 2 that has provided the TRIPS

ministre des Affaires étrangères, du ministre du Commerce international et du ministre de la Coopération internationale, modifier l'annexe 2, par adjonction du nom de tout pays qui, étant un pays moins avancé selon les Nations Unies, a transmis :

(i) s'il est membre de l'OMC, au Conseil des ADPIC un avis écrit de son intention d'importer, conformément à la décision du Conseil général, des produits pharmaceutiques au sens de l'alinéa 1a) de cette décision,

(ii) s'il n'est pas membre de l'OMC, au gouvernement du Canada, par la voie diplomatique, un avis écrit de son intention d'importer des produits pharmaceutiques au sens de l'alinéa 1a) de la décision du Conseil général, dans lequel il s'engage à ne pas utiliser les produits à des fins commerciales et à prendre les mesures visées à l'article 4 de cette décision;

c) sur recommandation du ministre des Affaires étrangères, du ministre du Commerce international et du ministre de la Coopération internationale, modifier l'annexe 3, par adjonction du nom de tout membre de l'OMC ne figurant pas à l'annexe 2 qui

- Council with a notice in writing stating that the WTO Member intends to import, in accordance with the General Council Decision, pharmaceutical products, as defined in paragraph 1(a) of that decision; and
- (d) on the recommendation of the Minister of Foreign Affairs, the Minister for International Trade and the Minister for International Cooperation, amend Schedule 4 by adding the name of
- (i) any WTO Member not listed in Schedule 2 or 3 that has provided the TRIPS Council with a notice in writing stating that the WTO Member intends to import, in accordance with the General Council Decision, pharmaceutical products, as defined in paragraph 1(a) of that decision, or
- (ii) any country that is not a WTO Member and that is named on the Organization for Economic Co-operation and Development's list of countries that are eligible for official development assistance and that has provided the Government of Canada with a notice in writing through diplomatic channels
- (A) stating that it is faced with a national emergency or other circumstances of extreme urgency,
- (B) specifying the name of
- a transmis au Conseil des ADPIC un avis écrit de son intention d'importer, conformément à la décision du Conseil général, des produits pharmaceutiques au sens de l'alinéa 1a) de cette décision;
- d) sur recommandation du ministre des Affaires étrangères, du ministre du Commerce international et du ministre de la Coopération internationale, modifier l'annexe 4, par adjonction :
- (i) du nom de tout membre de l'OMC ne figurant pas à l'annexe 2 ou 3 qui a transmis au Conseil des ADPIC un avis écrit de son intention d'importer, conformément à la décision du Conseil général, des produits pharmaceutiques au sens de l'alinéa 1a) de cette décision,
- (ii) du nom de tout pays non-membre de l'OMC qui figure sur la liste des pays admissibles à l'aide publique au développement établie par l'Organisation de coopération et de développement économiques, à la condition qu'il ait transmis au gouvernement du Canada, par la voie diplomatique, un avis écrit dans lequel il :
- (A) confirme qu'il fait face à une situation d'urgence nationale ou à d'autres circonstances d'extrême urgence,
- (B) précise le nom et la

the pharmaceutical product, as defined in paragraph 1(a) of the General Council Decision, and the quantity of that product, needed by the country to deal with the emergency or other urgency, (C) stating that it has no, or insufficient, pharmaceutical capacity to manufacture that product, and

(D) stating that it agrees that that product will not be used for commercial purposes and that it undertakes to adopt the measures referred to in Article 4 of the General Council Decision.

(2) The Governor in Council may not add to Schedule 3 the name of any WTO Member that has notified the TRIPS Council that it will import, in accordance with the General Council Decision, pharmaceutical products, as defined in paragraph 1(a) of that decision, only if faced with a national emergency or other circumstances of extreme urgency.

(3) The Governor in Council may, by order, on the recommendation of the Minister of Foreign Affairs, the Minister for International Trade and the Minister for International Cooperation, amend any of Schedules 2 to 4 to remove the name of any country or WTO Member if

quantité du produit pharmaceutique, au sens de l'alinéa 1a) de la décision du Conseil général, dont il a besoin pour y faire face,

(C) confirme qu'il n'a pas la capacité de fabrication du produit pharmaceutique ou que cette capacité est insuffisante,

(D) s'engage à ne pas utiliser le produit à des fins commerciales et à prendre les mesures visées à l'article 4 de cette décision.

(2) Le gouverneur en conseil ne peut ajouter à l'annexe 3 le nom d'un membre de l'OMC qui a avisé le Conseil des ADPIC de son intention de n'importer, conformément à la décision du Conseil général, des produits pharmaceutiques, au sens de l'alinéa 1a) de cette décision, que s'il fait face à une situation d'urgence nationale ou à d'autres circonstances d'extrême urgence.

(3) Sur recommandation du ministre des Affaires étrangères, du ministre du Commerce international et du ministre de la Coopération internationale, le gouverneur en conseil peut, par décret, supprimer de l'annexe 2, 3 ou 4 le nom d'un pays ou d'un membre de l'OMC si :

Restriction —
Schedule 3

Réserve —
annexe 3

Removal from
Schedules 2 to 4

Suppression —
annexes 2, 3 et 4

- (a) in the case of a country or WTO Member listed in Schedule 2, the country or WTO Member has ceased to be recognized by the United Nations as being a least-developed country or, in the case of a country that is not a WTO Member, the country has permitted any product imported into that country under an authorization to be used for commercial purposes or has failed to adopt the measures referred to in Article 4 of the General Council Decision;
- (b) in the case of a WTO Member listed in Schedule 3, the WTO Member has notified the TRIPS Council that it will import, in accordance with the General Council Decision, pharmaceutical products, as defined in paragraph 1(a) of that decision, only if faced with a national emergency or other circumstances of extreme urgency;
- (c) in the case of a WTO Member listed in Schedule 4, the WTO Member has revoked any notification it has given to the TRIPS Council that it will import pharmaceutical products, as defined in paragraph 1(a) of the General Council Decision, only if faced with a national emergency or other circumstances of extreme urgency;
- (d) in the case of a country listed in Schedule 4 that is
- a)* dans le cas de l'annexe 2, le pays ou le membre de l'OMC n'est plus, selon les Nations Unies, un pays moins avancé ou, s'il n'est pas membre de l'OMC, le pays a permis que tout produit importé au titre d'une autorisation soit utilisé à des fins commerciales ou n'a pas pris les mesures visées à l'article 4 de la décision du Conseil général;
- b)* dans le cas de l'annexe 3, le membre de l'OMC a avisé le Conseil des ADPIC de son intention de n'importer des produits pharmaceutiques, au sens de l'alinéa 1a) de la décision du Conseil général et conformément à celle-ci, que s'il fait face à une situation d'urgence nationale ou à d'autres circonstances d'extrême urgence;
- c)* dans le cas de l'annexe 4, le membre de l'OMC a révoqué l'avis donné au Conseil des ADPIC, selon lequel il a l'intention de n'importer des produits pharmaceutiques au sens de l'alinéa 1a) de la décision du Conseil général que s'il fait face à une situation d'urgence nationale ou à d'autres circonstances d'extrême urgence;
- d)* dans le cas de l'annexe 4, le pays non-membre de

- not a WTO Member,
- (i) the name of the country is no longer on the Organization for Economic Co-operation and Development's list of countries that are eligible for official development assistance,
- (ii) the country no longer faces a national emergency or other circumstances of extreme urgency,
- (iii) the country has permitted any product imported into that country under an authorization to be used for commercial purposes, or
- (iv) the country has failed to adopt the measures referred to in Article 4 of the General Council Decision;
- (e) in the case of any country or WTO Member listed in Schedule 3 or 4, the country or WTO Member has become recognized by the United Nations as a least-developed country; and
- (f) in the case of any country or WTO Member listed in any of Schedules 2 to 4, the country has notified the Government of Canada, or the WTO Member has notified the TRIPS Council, that it will not import pharmaceutical products, as defined in paragraph 1(a) of the General Council Decision.
- (4) An order under this section shall be made in a timely manner.
- l'OMC, selon le cas :
- (i) ne figure plus sur la liste des pays admissibles à l'aide publique au développement établie par l'Organisation de coopération et de développement économiques,
- (ii) ne fait plus face à une situation d'urgence nationale ou à d'autres circonstances d'extrême urgence,
- (iii) a permis que tout produit importé au titre d'une autorisation soit utilisé à des fins commerciales,
- (iv) n'a pas pris les mesures visées à l'article 4 de la décision du Conseil général;
- e) dans le cas de l'annexe 3 ou 4, le pays ou le membre de l'OMC est devenu un pays moins avancé selon les Nations Unies;
- f) dans le cas de l'annexe 2, 3 ou 4, le pays a avisé le gouvernement du Canada, ou le membre de l'OMC a avisé le Conseil des ADPIC, de son intention de ne pas importer de produits pharmaceutiques au sens de l'alinéa 1a) de la décision du Conseil général.
- (4) Tout décret visé au présent article doit être pris au moment opportun.

Authorization

21.04 (1) Subject to subsection (3), the Commissioner shall, on the application of any person and on the payment of the prescribed fee, authorize the person to make, construct and use a patented invention solely for purposes directly related to the manufacture of the pharmaceutical product named in the application and to sell it for export to a country or WTO Member that is listed in any of Schedules 2 to 4 and that is named in the application.

Contents of application

(2) The application must be in the prescribed form and set out

(a) the name of the pharmaceutical product to be manufactured and sold for export under the authorization;

(b) prescribed information in respect of the version of the pharmaceutical product to be manufactured and sold for export under the authorization;

(c) the maximum quantity of the pharmaceutical product to be manufactured and sold for export under the authorization;

(d) for each patented invention to which the application relates, the name of the patentee of the invention and the number, as recorded in the Patent Office, of the patent issued

Autorisation

21.04 (1) Sous réserve du paragraphe (3) et du paiement des taxes réglementaires, le commissaire autorise quiconque en fait la demande à utiliser, fabriquer et construire l'invention brevetée, pourvu que ce soit dans un but directement lié à la fabrication du produit pharmaceutique mentionné dans la demande, et à vendre celui-ci aux fins d'exportation vers le pays ou le membre de l'OMC mentionné dans celle-ci dont le nom figure à l'une des annexes 2, 3 ou 4.

Demande

(2) La demande doit être en la forme réglementaire et contenir les renseignements suivants :

a) le nom du produit pharmaceutique qui sera fabriqué et vendu aux fins d'exportation au titre de l'autorisation;

b) les renseignements réglementaires concernant la version du produit pharmaceutique en cause;

c) la quantité maximale prévue;

d) en ce qui touche toute invention brevetée visée par la demande, le nom du breveté et le numéro d'enregistrement du brevet au Bureau des brevets;

in respect of that invention;

(e) the name of the country or WTO Member to which the pharmaceutical product is to be exported;

(f) the name of the governmental person or entity, or the person or entity permitted by the government of the importing country, to which the product is to be sold, and prescribed information, if any, concerning that person or entity; and

(g) any other information that may be prescribed.

(3) The Commissioner shall authorize the use of the patented invention only if

(a) the applicant has complied with the prescribed requirements, if any;

(b) the Minister of Health has notified the Commissioner that the version of the pharmaceutical product that is named in the application meets the requirements of the *Food and Drugs Act* and its regulations, including the requirements under those regulations relating to the marking, embossing, labelling and packaging that identify that version of the product as having been manufactured

(i) in Canada as permitted by the General Council

e) le nom du pays ou du membre de l'OMC vers lequel le produit sera exporté;

f) le nom du représentant du gouvernement ou de l'entité gouvernementale, ou de la personne ou de l'entité permise par le gouvernement du pays importateur, à qui le produit sera vendu et tout autre renseignement éventuellement prévu par règlement à son égard;

g) tout autre renseignement éventuellement prévu par règlement.

(3) L'usage de l'invention brevetée ne peut être autorisé par le commissaire que si les conditions suivantes sont remplies :

a) le demandeur s'est conformé aux éventuelles exigences réglementaires;

b) le ministre de la Santé a notifié au commissaire le fait que la version du produit pharmaceutique mentionnée dans la demande satisfait aux exigences de la *Loi sur les aliments et drogues* et de ses règlements, notamment aux exigences réglementaires en matière de marquage, d'estampage, d'étiquetage et d'emballage qui indiquent que cette version du produit :

(i) est fabriquée au Canada au titre de la décision du

Conditions for
granting of
authorization

Conditions
d'octroi de
l'autorisation

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| <p>Decision, and</p> <p>(ii) in a manner that distinguishes it from the version of the pharmaceutical product sold in Canada by, or with the consent of, the patentee or patentees, as the case may be;</p> <p>(c) the applicant provides the Commissioner with a solemn or statutory declaration in the prescribed form stating that the applicant had, within thirty days before filing the application,</p> <p>(i) sought from the patentee or, if there is more than one, from each of the patentees, by certified or registered mail, a licence to manufacture and sell the pharmaceutical product for export to the country or WTO Member named in the application on reasonable terms and conditions and that such efforts have not been successful, and</p> <p>(ii) provided the patentee, or each of the patentees, as the case may be, by certified or registered mail, in the written request for a licence, with the information that is in all material respects identical to the information referred to in paragraphs (2)(a) to (g); and</p> <p>(d) the applicant also provides the Commissioner with</p> <p>(i) if the application relates to a WTO Member listed in Schedule 2, a certified copy</p> | <p>Conseil général,</p> <p>(ii) est différente de la version du produit pharmaceutique vendue au Canada par tout breveté ou avec son accord;</p> <p>c) le demandeur a fourni au commissaire une déclaration solennelle, en la forme réglementaire, selon laquelle, dans les trente jours précédant le dépôt de la demande, il a :</p> <p>(i) tenté d'obtenir une licence du breveté — ou de chacun des brevetés — par courrier certifié ou recommandé en vue de fabriquer et de vendre aux fins d'exportation le produit au pays ou au membre de l'OMC mentionné dans la demande à des conditions raisonnables,</p> <p>(ii) fourni au breveté — ou à chacun des brevetés — par courrier certifié ou recommandé, dans cette demande de licence, des renseignements qui sont, à tous égards importants, identiques à ceux énumérés aux alinéas (2)a) à g);</p> <p>d) le demandeur a également fourni au commissaire :</p> <p>(i) dans le cas d'une demande concernant un membre de l'OMC visé à</p> |
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of the notice in writing that the WTO Member has provided to the TRIPS Council specifying the name of the pharmaceutical product, as defined in paragraph 1(a) of the General Council Decision, and the quantity of that product, needed by the WTO Member, and

(A) a solemn or statutory declaration in the prescribed form by the person filing the application stating that the product to which the application relates is the product specified in the notice and that the product is not patented in that WTO Member, or

(B) a solemn or statutory declaration in the prescribed form by the person filing the application stating that the product to which the application relates is the product specified in the notice and a certified copy of the notice in writing that the WTO Member has provided to the TRIPS Council confirming that the WTO Member has, in accordance with Article 31 of the TRIPS Agreement and the provisions of the General Council Decision, granted or intends to grant a compulsory licence to use the invention pertaining to the product,

(ii) if the application relates to a country listed in Schedule 2 that is not a WTO Member, a certified

l'annexe 2, d'une part, une copie certifiée de l'avis écrit transmis au Conseil des ADPIC dans lequel le membre précise le nom et la quantité du produit pharmaceutique, au sens de l'alinéa 1a) de la décision du Conseil général, dont il a besoin et, d'autre part :

(A) soit une déclaration solennelle, en la forme réglementaire, dans laquelle lui-même affirme que le produit mentionné dans sa demande est le produit précisé dans l'avis et n'est pas un produit breveté sur le territoire du membre,

(B) soit, d'une part, une déclaration solennelle, en la forme réglementaire, dans laquelle lui-même affirme que le produit mentionné dans sa demande est le produit précisé dans l'avis et, d'autre part, une copie certifiée de l'avis écrit transmis au Conseil des ADPIC dans lequel le membre confirme qu'il a accordé ou accordera, conformément à l'article 31 de l'Accord sur les ADPIC et aux dispositions de la décision du Conseil général, la licence obligatoire nécessaire à l'utilisation de l'invention relative au produit,

(ii) dans le cas d'une demande concernant un pays visé à l'annexe 2 qui n'est pas membre de l'OMC,

- copy of the notice in writing that the country has provided to the Government of Canada through diplomatic channels specifying the name of the pharmaceutical product, as defined in paragraph 1(a) of the General Council Decision, and the quantity of that product, needed by the country, and
- (A) a solemn or statutory declaration in the prescribed form by the person filing the application stating that the product to which the application relates is the product specified in the notice and that the product is not patented in that country, or
- (B) a solemn or statutory declaration in the prescribed form by the person filing the application stating that the product to which the application relates is the product specified in the notice and a certified copy of the notice in writing that the country has provided to the Government of Canada through diplomatic channels confirming that the country has granted or intends to grant a compulsory licence to use the invention pertaining to the product,
- (iii) if the application relates to a WTO Member listed in Schedule 3, a certified copy of the notice in writing that the WTO Member has provided to the TRIPS
- d'une part, une copie certifiée de l'avis écrit transmis au gouvernement du Canada, par la voie diplomatique, dans lequel le pays précise le nom et la quantité du produit pharmaceutique, au sens de l'alinéa 1a) de la décision du Conseil général, dont il a besoin, et, d'autre part :
- (A) soit une déclaration solennelle, en la forme réglementaire, dans laquelle lui-même affirme que le produit mentionné dans sa demande est le produit précisé dans l'avis et n'est pas un produit breveté sur le territoire du pays,
- (B) soit, d'une part, une déclaration solennelle, en la forme réglementaire, dans laquelle lui-même affirme que le produit mentionné dans sa demande est le produit précisé dans l'avis et, d'autre part, une copie certifiée de l'avis écrit transmis au gouvernement du Canada, par la voie diplomatique, dans lequel le pays confirme qu'il a accordé ou accordera la licence obligatoire nécessaire à l'utilisation de l'invention relative au produit,
- (iii) dans le cas d'une demande concernant un membre de l'OMC visé à l'annexe 3, d'une part, une copie certifiée de l'avis écrit transmis au Conseil des

Council specifying the name of the pharmaceutical product, as defined in paragraph 1(a) of the General Council Decision, and the quantity of that product, needed by the WTO Member, and stating that the WTO Member has insufficient or no pharmaceutical manufacturing capacity for the production of the product to which the application relates, and

(A) a solemn or statutory declaration in the prescribed form by the person filing the application stating that the product to which the application relates is not patented in that WTO Member, or

(B) a certified copy of the notice in writing that the WTO Member has provided to the TRIPS Council confirming that the WTO Member has, in accordance with Article 31 of the TRIPS Agreement and the provisions of the General Council Decision, granted or intends to grant a compulsory licence to use the invention pertaining to the product,

(iv) if the application relates to a WTO Member listed in Schedule 4, a certified copy of the notice in writing that the WTO Member has provided to the TRIPS Council specifying the name of the pharmaceutical product, as defined in

ADPIC dans lequel le membre précise le nom et la quantité du produit pharmaceutique, au sens de l'alinéa 1a) de la décision du Conseil général, dont il a besoin et confirme qu'il n'a pas la capacité de fabrication du produit visé par la demande ou que cette capacité est insuffisante, et, d'autre part :

(A) soit une déclaration solennelle, en la forme réglementaire, dans laquelle lui-même affirme que le produit mentionné dans sa demande n'est pas un produit breveté sur le territoire du membre,

(B) soit une copie certifiée de l'avis écrit transmis au Conseil des ADPIC dans lequel le membre confirme qu'il a accordé ou accordera, conformément à l'article 31 de l'Accord sur les ADPIC et aux dispositions de la décision du Conseil général, la licence obligatoire nécessaire à l'utilisation de l'invention relative au produit,

(iv) dans le cas d'une demande concernant un membre de l'OMC visé à l'annexe 4, d'une part, une copie certifiée de l'avis écrit transmis au Conseil des ADPIC dans lequel le membre précise le nom et la quantité du produit

paragraph 1(a) of the General Council Decision, and the quantity of that product, needed by the WTO Member, and stating that the WTO Member is faced with a national emergency or other circumstances of extreme urgency and that it has insufficient or no pharmaceutical manufacturing capacity for the production of the product to which the application relates, and

(A) a solemn or statutory declaration in the prescribed form by the person filing the application stating that the product to which the application relates is not patented in that WTO Member, or

(B) a certified copy of the notice in writing that the WTO Member has provided to the TRIPS Council confirming that the WTO Member has, in accordance with Article 31 of the TRIPS Agreement and the provisions of the General Council Decision, granted or intends to grant a compulsory licence to use the invention pertaining to the product, or

(v) if the application relates to a country listed in Schedule 4 that is not a WTO Member, a certified copy of the notice in writing that the country has provided to the Government of Canada through

pharmaceutique, au sens de l'alinéa 1a) de la décision du Conseil général, dont il a besoin et confirme qu'il fait face à une situation d'urgence nationale ou à d'autres circonstances d'extrême urgence et qu'il n'a pas la capacité de fabrication du produit visé par la demande ou que cette capacité est insuffisante, et, d'autre part :

(A) soit une déclaration solennelle, en la forme réglementaire, dans laquelle lui-même affirme que le produit mentionné dans sa demande n'est pas un produit breveté sur le territoire du membre,

(B) soit une copie certifiée de l'avis écrit transmis au Conseil des ADPIC dans lequel le membre confirme qu'il a accordé ou accordera, conformément à l'article 31 de l'Accord sur les ADPIC et aux dispositions de la décision du Conseil général, la licence obligatoire nécessaire à l'utilisation de l'invention relative au produit,

(v) dans le cas d'une demande concernant un pays visé à l'annexe 4 qui n'est pas membre de l'OMC, d'une part, une copie certifiée de l'avis écrit transmis au gouvernement du Canada, par la voie

diplomatic channels specifying the name of the pharmaceutical product, as defined in paragraph 1(a) of the General Council Decision, and the quantity of that product, needed by the country, and stating that it is faced with a national emergency or other circumstances of extreme urgency, that it has insufficient or no pharmaceutical manufacturing capacity for the production of the product to which the application relates, that it agrees that product will not be used for commercial purposes and that it undertakes to adopt the measures referred to in Article 4 of the General Council Decision, and

(A) a solemn or statutory declaration in the prescribed form by the person filing the application stating that the product to which the application relates is not patented in that country, or

(B) a certified copy of the notice in writing that the country has provided to the Government of Canada through diplomatic channels confirming that the country has granted or intends to grant a compulsory licence to use the invention pertaining to the product.

21.05 (1) The authorization must be in the prescribed form and, subject

diplomatique, dans lequel le pays précise le nom et la quantité du produit pharmaceutique, au sens de l'alinéa 1a) de la décision du Conseil général, dont il a besoin, confirme qu'il fait face à une situation d'urgence nationale ou à d'autres circonstances d'extrême urgence et qu'il n'a pas la capacité de fabrication du produit visé par la demande ou que cette capacité est insuffisante et s'engage à ne pas utiliser le produit à des fins commerciales et à prendre les mesures visées à l'article 4 de cette décision et, d'autre part :

(A) soit une déclaration solennelle, en la forme réglementaire, dans laquelle lui-même affirme que le produit mentionné dans sa demande n'est pas un produit breveté sur le territoire du pays,

(B) soit une copie certifiée de l'avis écrit transmis au gouvernement du Canada, par la voie diplomatique, dans lequel le pays confirme qu'il a accordé ou accordera la licence obligatoire nécessaire à l'utilisation de l'invention relative au produit.

21.05 (1) L'autorisation doit être en la forme réglementaire et, sous

	to subsection (2), contain the prescribed information.	réserve du paragraphe (2), contenir les renseignements prévus par règlement.	
Quantity	(2) The quantity of the product authorized to be manufactured by an authorization may not be more than the lesser of (a) the maximum quantity set out in the application for the authorization, and (b) the quantity set out in the notice referred to in any of subparagraphs 21.04(3)(d)(i) to (v), whichever is applicable.	(2) La quantité de produit dont la fabrication est autorisée ne peut être supérieure à la plus petite des quantités suivantes : a) la quantité maximale mentionnée dans la demande d'autorisation; b) la quantité mentionnée dans l'avis prévu à l'un des sous-alinéas 21.04(3)d(i) à (v), selon le cas.	Quantité
Disclosure of information on website	21.06 (1) Before exporting a product manufactured under an authorization, the holder of the authorization must establish a website on which is disclosed the prescribed information respecting the name of the product, the name of the country or WTO Member to which it is to be exported, the quantity that is authorized to be manufactured and sold for export and the distinguishing features of the product, and of its label and packaging, including all known participants in the logistical chain from Canada to the importing country, as required by regulations made under the <i>Food and Drugs Act</i> .	21.06 (1) Avant d'exporter le produit fabriqué au titre de l'autorisation, le titulaire doit créer un site Internet et y afficher les renseignements réglementaires concernant le nom du produit, le nom du pays ou du membre de l'OMC vers lequel le produit sera exporté, la quantité qu'il est autorisé à fabriquer et à vendre aux fins d'exportation ainsi que les caractères distinctifs du produit et de son étiquetage et emballage y compris tous les intervenants connus de la chaîne logistique du Canada au pays importateur, exigés par les règlements pris en vertu de la <i>Loi sur les aliments et drogues</i> .	Affichage sur site Internet
Obligation to maintain	(2) The holder must maintain the website during the entire period during which the authorization is valid.	(2) Le titulaire est tenu de conserver le site pendant toute la durée de l'autorisation.	Obligation
Links to other websites	(3) The Commissioner of	(3) Le commissaire aux	Liens Internet

Posting on the website	<p>Patents shall post and maintain on the website of the Canadian Intellectual Property Office a link to each website required to be maintained by the holder of an authorization under subsection (1).</p>	<p>brevets affichera et gardera sur le site Internet de l'Office de la propriété intellectuelle du Canada un lien vers chaque site Internet devant être maintenu par le titulaire d'une autorisation en vertu du paragraphe (1).</p>	Affichage sur le site Internet
Export notice	<p>(4) The Commissioner of Patents shall, within seven days of receipt, post on the website of the Canadian Intellectual Property Office each application for authorization filed under section 21.04(1).</p>	<p>(4) Dans les sept jours de la réception d'une demande d'autorisation donnée en vertu de l'article 21.04(1), le commissaire aux brevets affichera cette demande sur le site Internet de l'Office de la propriété intellectuelle du Canada.</p>	Avis d'exportation
Royalty	<p>21.07 Before each shipment of any quantity of a product manufactured under an authorization, the holder of the authorization must, within fifteen days before the product is exported, provide to each of the following a notice, by certified or registered mail, specifying the quantity to be exported, and identifying every known party in the distribution chain from Canada to the final country of import:</p> <p>(a) the patentee or each of the patentees, as the case may be;</p> <p>(b) the country or WTO Member named in the authorization; and</p> <p>(c) the person or entity that purchased the product to which the authorization relates.</p>	<p>21.07 Avant chaque expédition d'une quantité du produit fabriqué au titre de l'autorisation, le titulaire donne par courrier certifié ou recommandé, dans les quinze jours précédant l'exportation, avis de la quantité en cause et de l'identité de toute partie connue faisant partie de la chaîne de distribution depuis le Canada jusqu'au dernier pays importateur :</p> <p>a) au breveté ou à chacun des brevetés, selon le cas;</p> <p>b) au pays ou au membre de l'OMC mentionné dans l'autorisation;</p> <p>c) à la personne ou à l'entité qui a acheté le produit visé par celle-ci.</p>	Redevances
	<p>21.08 (1) Subject to subsections (3) and (4), on the occurrence of a</p>	<p>21.08 (1) Sous réserve des paragraphes (3) et (4), le titulaire de l'autorisation est</p>	

Factors to consider when making regulations	prescribed event, the holder of an authorization is required to pay to the patentee or each patentee, as the case may be, a royalty determined in the prescribed manner.	tenu de verser, à la survenance de tout événement visé par règlement, au breveté — ou à chacun des brevetés — la redevance déterminée de la manière réglementaire.	Critère — règlements
Time for payment	(2) In making regulations for the purposes of subsection (1), the Governor in Council must consider the humanitarian and non-commercial reasons underlying the issuance of authorizations under subsection 21.04(1).	(2) Pour la prise de tout règlement au titre du paragraphe (1), le gouverneur en conseil prend en considération le fait que l'octroi d'autorisations au titre du paragraphe 21.04(1) est fondé sur des motifs humanitaires et non commerciaux.	Modalités de temps
Federal Court may determine royalty	(3) The royalties payable under this section must be paid within the prescribed time.	(3) Le titulaire est tenu de verser les redevances dans le délai réglementaire.	Fixation de la redevance par la Cour fédérale
Application and notice	(4) The Federal Court may, in relation to any authorization, make an order providing for the payment of a royalty that is greater than the royalty that would otherwise be required to be paid under subsection (1).	(4) La Cour fédérale peut, par ordonnance, prévoir le versement d'une redevance dont le montant dépasse celui établi au titre du paragraphe (1).	Demande et avis
Contents of order	(5) An order may be made only on the application of the patentee, or one of the patentees, as the case may be, and on notice of the application being given by the applicant to the holder of the authorization.	(5) L'ordonnance ne peut être rendue que sur demande présentée par le breveté, ou l'un des brevetés, et qu'après signification de celle-ci au titulaire de l'autorisation.	Contenu de l'ordonnance
Conditions for making of order	(6) An order may provide for a royalty of a fixed amount or for a royalty to be determined as specified in the order, and the order may be subject to any terms that the Federal Court considers appropriate.	(6) L'ordonnance peut soit préciser le montant de la redevance, soit en prévoir les modalités de détermination, et être assortie des conditions que le tribunal juge indiquées.	Conditions
	(7) The Federal Court	(7) Le tribunal ne peut	

	<p>may make an order only if it is satisfied that the royalty otherwise required to be paid is not adequate remuneration for the use of the invention or inventions to which the authorization relates, taking into account</p> <p>(a) the humanitarian and non-commercial reasons underlying the issuance of the authorization; and</p> <p>(b) the economic value of the use of the invention or inventions to the country or WTO Member.</p>	<p>rendre l'ordonnance que s'il est convaincu que la redevance en question n'est pas une rémunération adéquate pour l'usage de toute invention visée par l'autorisation, compte tenu des éléments suivants :</p> <p>a) les motifs — humanitaires et non commerciaux — pour lesquels l'autorisation a été octroyée;</p> <p>b) la valeur économique de l'usage de l'invention pour le pays ou le membre de l'OMC.</p>	
Duration	<p>21.09 An authorization granted under subsection 21.04(1) is valid for a period of two years beginning on the day on which the authorization is granted.</p>	<p>21.09 L'autorisation est valide pour une période de deux ans, à compter de la date de son octroi au titre du paragraphe 21.04(1).</p>	Durée de l'autorisation
Use is non-exclusive	<p>21.1 The use of a patented invention under an authorization is non-exclusive.</p>	<p>21.1 L'usage de l'invention brevetée au titre d'une autorisation ne peut être exclusif.</p>	Usage non exclusif
Authorization is non-transferable	<p>21.11 An authorization is non-transferable, other than where the authorization is an asset of a corporation or enterprise and the part of the corporation or enterprise that enjoys the use of the authorization is sold, assigned or otherwise transferred.</p>	<p>21.11 L'autorisation est incessible, sauf si la partie de la personne morale ou de l'entreprise qui a la jouissance de cet élément d'actif est vendue, cédée ou transférée.</p>	Autorisation incessible
Renewal	<p>21.12 (1) The Commissioner shall, on the application of the person to whom an authorization was granted and on the payment of the prescribed fee, renew the authorization if the person certifies under oath in the renewal application</p>	<p>21.12 (1) Sur demande et paiement des taxes réglementaires, le commissaire renouvelle l'autorisation si le demandeur certifie sous serment dans la demande que la quantité de produit pharmaceutique visée par</p>	Renouvellement de l'autorisation

	that the quantities of the pharmaceutical product authorized to be exported were not exported before the authorization ceases to be valid and that the person has complied with the terms of the authorization and the requirements of sections 21.06 to 21.08.	l'autorisation n'a pas été exportée en totalité au moment de la cessation de validité de celle-ci et qu'il en a respecté les conditions et s'est conformé aux articles 21.06 à 21.08.	
One renewal	(2) An authorization may be renewed only once.	(2) L'autorisation ne peut être renouvelée qu'une seule fois.	Un seul renouvellement
When application must be made	(3) The application for renewal must be made within the 30 days immediately before the authorization ceases to be valid.	(3) La demande de renouvellement doit être faite au cours des trente jours précédant la cessation de validité de l'autorisation.	Délai
Duration	(4) An authorization that is renewed is valid for a period of two years beginning on the day immediately following the day of the expiry of the period referred to in section 21.09 in respect of the authorization.	(4) L'autorisation renouvelée est valide pour une période de deux ans, à compter du jour suivant celui où expire la période prévue à l'article 21.09.	Durée
Prescribed form	(5) Applications for renewal and renewed authorizations issued under subsection (1) must be in the prescribed form.	(5) La demande de renouvellement et l'autorisation renouvelée doivent être en la forme réglementaire.	Forme réglementaire
Termination	21.13 Subject to section 21.14, an authorization ceases to be valid on the earliest of (a) the expiry of the period referred to in section 21.09 in respect of the authorization, or the expiry of the period referred to in subsection 21.12(4) if the authorization has been renewed, as the case may be,	21.13 Sous réserve de l'article 21.14, l'autorisation cesse d'être valide le premier en date des jours suivants : a) le jour de l'expiration de la période prévue à l'article 21.09 ou, en cas de renouvellement de l'autorisation, de la période prévue au paragraphe 21.12(4);	Expiration de l'autorisation

- (b) the day on which the Commissioner sends, by registered mail, to the holder of the authorization a copy of a notice sent by the Minister of Health notifying the Commissioner that the Minister of Health is of the opinion that the pharmaceutical product referred to in paragraph 21.04(3)(b) has ceased to meet the requirements of the *Food and Drugs Act* and its regulations,
- (c) the day on which the last of the pharmaceutical product authorized by the authorization to be exported is actually exported,
- (d) thirty days after the day on which
- (i) the name of the pharmaceutical product authorized to be exported by the authorization is removed from Schedule 1, or
- (ii) the name of the country or WTO Member to which the pharmaceutical product was, or is to be, exported is removed from Schedule 2, 3 or 4, as the case may be, and not added to any other of those Schedules, and
- (e) on any other day that is prescribed.
- 21.14** On the application of a patentee, and on notice given by the patentee to the person to whom an authorization was granted, the Federal Court may make an order, on any terms that it considers appropriate, terminating the
- b) le jour où le commissaire envoie par courrier recommandé au titulaire de l'autorisation copie de l'avis transmis par le ministre de la Santé selon lequel celui-ci est d'avis que le produit pharmaceutique visé à l'alinéa 21.04(3)b) ne satisfait plus aux exigences de la *Loi sur les aliments et drogues* et de ses règlements;
- c) le jour où la totalité des produits pharmaceutiques visés par l'autorisation a été exportée;
- d) le trentième jour suivant le jour de la suppression :
- (i) à l'annexe 1, du nom du produit pharmaceutique visé par l'autorisation,
- (ii) à l'une des annexes 2, 3 ou 4, du nom du pays ou du membre de l'OMC visé par l'autorisation, si son nom n'est pas ajouté à une autre annexe;
- e) le jour établi selon les règlements.
- 21.14** Sur demande du breveté et après avis donné par celui-ci au titulaire de l'autorisation, la Cour fédérale peut rendre une ordonnance assortie des conditions qu'elle estime indiquées et mettant fin à l'autorisation si le breveté

- authorization if the patentee establishes that
- (a)* the application for the authorization or any of the documents provided to the Commissioner in relation to the application contained any material information that is inaccurate;
- (b)* the holder of the authorization has failed to establish a website as required by section 21.06, has failed to disclose on that website the information required to be disclosed by that section or has failed to maintain the website as required by that section;
- (c)* the holder of the authorization has failed to provide a notice required to be given under section 21.07;
- (d)* the holder of the authorization has failed to pay, within the required time, any royalty required to be paid as a result of the authorization;
- (e)* the holder of the authorization has failed to comply with subsection 21.16(2);
- (f)* the product exported to the country or WTO Member, as the case may be, under the authorization has been, with the knowledge of the holder of the authorization, re-exported in a manner that is contrary to the General Council Decision;
- (g)* the product was exported, other than in the
- établit que, selon le cas :
- a)* la demande d'autorisation ou tout document fourni au commissaire à cet égard contenait des renseignements inexacts sur des points importants;
- b)* le titulaire n'a pas établi le site Internet exigé par l'article 21.06, n'y a pas affiché les renseignements prescrits ou ne l'a pas conservé tel que l'exige cet article;
- c)* celui-ci n'a pas donné les avis exigés par l'article 21.07;
- d)* celui-ci n'a pas acquitté les redevances dans le délai prescrit;
- e)* celui-ci ne s'est pas conformé au paragraphe 21.16(2);
- f)* le produit exporté au titre de l'autorisation vers le pays ou le membre de l'OMC a été réexportée, en contravention de la décision du Conseil général et au su du titulaire;
- g)* sauf le cas du transit, le produit a été exporté vers un

normal course of transit, to a country or WTO Member other than the country or WTO Member named in the authorization;

(h) the product was exported in a quantity greater than the quantity authorized to be manufactured; or

(i) if the product was exported to a country that is not a WTO Member, the country has permitted the product to be used for commercial purposes or has failed to adopt the measures referred to in Article 4 of the General Council Decision.

21.15 The Commissioner shall, without delay, notify the patentee, or each of the patentees, as the case may be, in writing of any authorization granted in respect of the patentee's invention.

21.16 (1) Within fifteen days after the later of the day on which the authorization was granted and the day on which the agreement for the sale of the product to which the authorization relates was entered into, the holder of an authorization must provide by certified or registered mail, the Commissioner and the patentee, or each patentee, as the case may be, with

(a) a copy of the agreement it has reached with the person or entity referred to in 21.04(2)(f) for the supply of the product authorized to

pays ou un membre de l'OMC autre que celui mentionné dans la demande;

h) la quantité exportée du produit est supérieure à celle dont la fabrication est autorisée;

i) dans le cas où le produit a été exporté vers un pays non-membre de l'OMC, le pays a permis que le produit soit utilisé à des fins commerciales ou n'a pas pris les mesures visées à l'article 4 de la décision du Conseil général.

21.15 Le commissaire avise sans délai et par écrit le breveté, ou chacun des brevetés, de toute autorisation accordée à l'égard de son invention.

21.16 (1) Dans les quinze jours suivant le jour de l'octroi de l'autorisation ou de la conclusion de l'accord concernant la vente du produit visé par l'autorisation, le dernier délai à expirer étant à retenir, le titulaire de l'autorisation envoie par courrier certifié ou recommandé au commissaire et au breveté — ou à chacun des brevetés :

a) une copie de l'accord qu'il a conclu avec la personne ou l'entité visée à l'alinéa 21.04(2)(f) pour fournir le produit dont la

Notice to patentee

Obligation to provide copy of agreement

Avis

Obligation de fournir une copie de l'accord

	<p>be manufactured and sold incorporating information that is in all material respects identical to the information referred to in paragraphs (2)(a), (b), (e) and (f); and</p> <p>(b) a solemn or statutory declaration in the prescribed form setting out</p> <p>(i) the total monetary value of the agreement as it relates to the product authorized to be manufactured and sold, expressed in Canadian currency, and</p> <p>(ii) the number of units of the product to be sold under the terms of the agreement.</p>	<p>fabrication et la vente sont autorisées, incluant des renseignements qui sont, à tous égards importants, identiques à ceux énumérés aux alinéas (2)a, b, e) et f);</p> <p>b) une déclaration solennelle, en la forme réglementaire, précisant :</p> <p>(i) la valeur pécuniaire de l'accord, relativement au produit dont la fabrication et la vente sont autorisées, exprimée en monnaie canadienne,</p> <p>(ii) le nombre d'unités du produit à vendre aux termes de l'accord.</p>	
Prohibition	<p>(2) The holder of an authorization may not export any product to which the authorization relates until after the holder has complied with subsection (1).</p>	<p>(2) Le titulaire ne peut exporter le produit visé par l'autorisation tant qu'il ne s'est pas conformé au paragraphe (1).</p>	Interdiction
Application when agreement is commercial in nature	<p>21.17 (1) If the average price of the product to be manufactured under an authorization is equal to or greater than 25 per cent of the average price in Canada of the equivalent product sold by or with the consent of the patentee, the patentee may, on notice given by the patentee to the person to whom an authorization was granted, apply to the Federal Court for an order under subsection (3) on the grounds that the essence of the agreement under which the product is to be sold is commercial in nature.</p>	<p>21.17 (1) Dans le cas où le prix moyen du produit à fabriquer au titre de l'autorisation est égal ou supérieur à vingt-cinq pour cent du prix moyen au Canada du produit équivalent vendu par le breveté ou avec son consentement, celui-ci peut, après avis donné au titulaire de l'autorisation, demander à la Cour fédérale de rendre une ordonnance au titre du paragraphe (3) au motif que l'accord aux termes duquel le produit sera vendu est par essence de nature commerciale.</p>	Demande — accord de nature commerciale
Factors for determining whether agreement	<p>(2) In determining</p>	<p>(2) Pour décider de la</p>	Nature commerciale de l'accord —

is commercial in nature

whether the agreement is commercial in nature, the Federal Court must take into account

(a) the need for the holder of the authorization to make a reasonable return sufficient to sustain a continued participation in humanitarian initiatives;

(b) the ordinary levels of profitability, in Canada, of commercial agreements involving pharmaceutical products, as defined in paragraph 1(a) of the General Council Decision; and

(c) international trends in prices as reported by the United Nations for the supply of such products for humanitarian purposes.

Order

(3) If the Federal Court determines that the agreement is commercial in nature, it may make an order, on any terms that it considers appropriate,

(a) terminating the authorization; or

(b) requiring the holder to pay, in addition to the royalty otherwise required to be paid, an amount that the Federal Court considers adequate to compensate the patentee for the commercial use of the patent.

Additional order

(4) If the Federal Court makes an order terminating the authorization, the Federal Court may also, if it considers it appropriate to do so, make an order, on any

nature commerciale d'un accord, le tribunal tient compte :

a) du fait que le titulaire de l'autorisation doit obtenir un juste rendement pour pouvoir continuer à participer aux initiatives humanitaires;

b) des niveaux de rentabilité au Canada des accords commerciaux relatifs aux produits pharmaceutiques, au sens de l'alinéa 1a) de la décision du Conseil général;

c) des tendances internationales concernant les prix, selon les Nations Unies, de tels produits fournis à des fins humanitaires.

facteurs

Ordonnance

(3) S'il conclut que l'accord est de nature commerciale, le tribunal peut rendre une ordonnance, assortie des conditions qu'il estime indiquées :

a) mettant fin à l'autorisation;

b) exigeant du titulaire qu'il verse au breveté, outre les redevances, une indemnité appropriée pour l'utilisation commerciale du brevet.

Ordonnance additionnelle

(4) S'il met fin à l'autorisation, le tribunal peut rendre une ordonnance, assortie des conditions qu'il estime indiquées :

terms that it considers appropriate,

(a) requiring the holder to deliver to the patentee any of the product to which the authorization relates remaining in the holder's possession as though the holder had been determined to have been infringing a patent; or

(b) with the consent of the patentee, requiring the holder to export any of the product to which the authorization relates remaining in the holder's possession to the country or WTO Member named in the authorization.

Restriction

(5) The Federal Court may not make an order under subsection (3) if, under the protection of a confidentiality order made by the Court, the holder of the authorization submits to a Court-supervised audit and that audit establishes that the average price of the product manufactured under the authorization does not exceed an amount equal to the direct supply cost of the product plus 15 per cent of that direct supply cost.

Definitions

(6) The following definitions apply in this section.

"average price"
« *prix moyen* »

verage price" means

a) exigeant du titulaire qu'il livre au breveté les produits visés par l'autorisation qui sont en sa possession, comme s'il avait été statué qu'il avait contrefait un brevet;

b) exigeant du titulaire, si le breveté y consent, qu'il exporte, vers le pays ou le membre de l'OMC mentionné dans la demande, les produits visés par l'autorisation qui sont en sa possession.

Réserve

(5) Il ne peut être rendu d'ordonnance au titre du paragraphe (3) si le titulaire de l'autorisation se soumet à une vérification ordonnée par le tribunal sous le sceau de la confidentialité et que la vérification établit que le prix moyen du produit pharmaceutique à fabriquer au titre de l'autorisation n'excède pas le coût direct de fourniture du produit, plus quinze pour cent de ce coût.

Définitions

(6) Les définitions qui suivent s'appliquent au présent article.

coût direct de fourniture »
S'agissant du produit à fabriquer au titre de l'autorisation, les coûts des matériaux et de la main d'oeuvre, et les autres coûts de fabrication, directement

« coût direct de
fourniture »
"direct supply
cost"

liés à la production de la quantité du produit.

prix moyen » :

(a) in relation to a product to be manufactured under an authorization, the total monetary value of the agreement under which the product is to be sold, expressed in Canadian currency, divided by the number of units of the product to be sold under the terms of the agreement; and

(b) in relation to an equivalent product sold by or with the consent of the patentee, the average of the prices in Canada of that product as those prices are reported in prescribed publications on the day on which the application for the authorization was filed.

“direct supply cost”
« coût direct de fourniture »

irect supply cost”, in relation to a product to be manufactured under an authorization, means the cost of the materials and of the labour, and any other manufacturing costs, directly related to the production of the quantity of the product that is to be manufactured under the authorization.

“unit”
« unité »

nit”, in relation to any product, means a single tablet, capsule or other individual dosage form of the product, and if applicable, in a particular strength.

Advisory committee

21.18 (1) The Minister and the Minister of Health shall establish, within three years, an advisory

a) S’agissant du produit à fabriquer au titre de l’autorisation, le nombre obtenu par division de la valeur pécuniaire de l’accord — exprimée en monnaie canadienne — par le nombre d’unités du produit à vendre aux termes de celui-ci;

b) s’agissant du produit équivalent vendu par le breveté ou avec son consentement, le nombre correspondant à la moyenne des prix au Canada du produit qui figurent, le jour du dépôt de la demande d’autorisation, dans les publications visées par règlement.

« unité »
“unit”

unité » Plus petite quantité individuelle d’un produit dans telle forme posologique — comprimé, gélule ou autre — et, le cas échéant, dans telle concentration.

Comité consultatif

21.18 (1) Le ministre et le ministre de la Santé constituent, dans un délai de trois ans, un comité

Functions of standing committee	committee to advise them on the recommendations that they may make to the Governor in Council respecting the amendment of Schedule 1.	consultatif chargé de les conseiller relativement aux recommandations à faire au gouverneur en conseil concernant toute modification de l'annexe 1.	Fonctions du comité permanent
	(2) The standing committee of the House of Commons that normally considers matters related to industry shall assess all candidates for appointment to the advisory committee and make recommendations to the Minister on the eligibility and qualifications of those candidates.	(2) Le comité permanent de la Chambre des communes habituellement chargé des questions concernant l'industrie évalue les candidats en vue de leur nomination à un poste au comité consultatif et présente au ministre des recommandations quant à leur admissibilité et leur qualification.	
Website for notices to Canada	21.19 The person designated by the Governor in Council for the purpose of this section must maintain a website on which is set out a copy of every notice referred to in subparagraphs 21.04(3)(d)(ii) and (v) that is provided to the Government of Canada through diplomatic channels by a country that is not a WTO Member. The copy must be added to the website as soon as possible after the notice has been provided to the Government of Canada.	21.19 La personne désignée par le gouverneur en conseil pour l'application du présent article doit créer un site Internet et y afficher copie de tout avis écrit mentionné aux sous-alinéas 21.04(3)d(ii) et (v) qui a été transmis, par la voie diplomatique, au gouvernement du Canada par tout pays non-membre de l'OMC. Elle affiche la copie dans les meilleurs délais après la réception de l'avis par le gouvernement du Canada.	Établissement d'un site Internet
Review	21.2 (1) A review of sections 21.01 to 21.19 and their application must be completed by the Minister two years after this section comes into force.	21.2 (1) Le ministre effectue l'examen des articles 21.01 à 21.19 et de leur application dans les deux ans suivant l'entrée en vigueur du présent article.	Examen
Tabling of report	(2) The Minister must cause a report of the results of the review to be laid before each House of Parliament on any of the	(2) Le ministre fait déposer le rapport devant chaque chambre du Parlement dans les quinze jours de séance de celle-ci	Dépôt du rapport

first fifteen days on which that House is sitting after the report has been completed.

R.S., c. F-27

FOOD AND DRUGS ACT

2. Section 30 of the *Food and Drugs Act* is amended by adding the following after subsection (4):

Regulations to implement the General Council Decision

(5) Without limiting or restricting the authority conferred by any other provisions of this Act or any of its Parts for carrying into effect the purposes and provisions of this Act or any of its Parts, the Governor in Council may make any regulations that the Governor in Council considers necessary for the purpose of implementing the General Council Decision.

Definitions

(6) The definitions in this subsection apply in this subsection and in subsection (5).

“General Council
»
« *Conseil général*
»

“General Council” means the General Council of the WTO established by paragraph 2 of Article IV of the Agreement Establishing the World Trade Organization, signed at Marrakesh on April 15, 1994.

“General Council
Decision”
« *décision du
Conseil général* »

“General Council Decision” means the decision of the General Council of August 30, 2003 respecting Article 31 of the TRIPS Agreement, including the interpretation of that decision in the General Council

suivant l’établissement du rapport.

L.R., ch. F-27

**LOI SUR LES ALIMENTS ET
DROGUES**

2. L’article 30 la *Loi sur les aliments et drogues* est modifié par adjonction, après le paragraphe (4), de ce qui suit :

Règlements relatifs à la décision du Conseil général

(5) Sans que soit limité le pouvoir conféré par toute autre disposition de la présente loi de prendre des règlements d’application de tout ou partie de celle-ci, le gouverneur en conseil peut prendre les règlements qu’il estime nécessaires pour la mise en oeuvre de la décision du Conseil général.

Définitions

(6) Les définitions qui suivent s’appliquent au présent paragraphe et au paragraphe (5).

« Accord sur les
ADPIC »
« *TRIPS
Agreement* »

« Accord sur les ADPIC » L’Accord sur les aspects des droits de propriété intellectuelle qui touchent au commerce, figurant à l’annexe 1C de l’Accord instituant l’Organisation mondiale du commerce signé à Marrakech le 15 avril 1994.

« Conseil
général »
« *General
Council* »

« Conseil général » Le Conseil général de l’OMC créé par le paragraphe 2 de l’article IV de l’Accord instituant l’Organisation mondiale du commerce, signé à Marrakech le 15 avril 1994.

Chairperson's statement of that date.

"TRIPS Agreement"
« Accord sur les ADPIC »

"TRIPS Agreement" means the Agreement on Trade-Related Aspects of Intellectual Property Rights, being Annex 1C of the Agreement Establishing the World Trade Organization, signed at Marrakesh on April 15, 1994.

décision du Conseil général » La décision rendue le 30 août 2003 par le Conseil général à l'égard de l'article 31 de l'Accord sur les ADPIC, y compris l'interprétation donnée de celle-ci dans la déclaration de son président faite le même jour.

« décision du Conseil général »
"General Council Decision"

"WTO"
« OMC »

"WTO" means the World Trade Organization established by Article I of the Agreement Establishing the World Trade Organization, signed at Marrakesh on April 15, 1994.

OMC » L'Organisation mondiale du commerce constituée par l'article I de l'Accord instituant l'Organisation mondiale du commerce, signé à Marrakech le 15 avril 1994.

« OMC »
"WTO"

3. Section 37 of the Act is amended by adding the following after subsection (1):

3. L'article 37 de la même loi est modifié par adjonction, après le paragraphe (1), de ce qui suit :

Exception —
General Council
Decision

(2) Despite subsection (1), this Act applies in respect of any drug or device to be manufactured for the purpose of being exported in accordance with the General Council Decision, as defined in subsection 30(6), and the requirements of the Act and the regulations apply to the drug or device as though it were a drug or device to be manufactured and sold for consumption in Canada, unless the regulations provide otherwise.

(2) Malgré le paragraphe (1), la présente loi s'applique aux drogues et instruments à fabriquer en vue de leur exportation conformément à la décision du Conseil général, au sens du paragraphe 30(6). Les exigences prévues par la présente loi et par ses règlements s'appliquent aux drogues et instruments comme s'ils étaient destinés à être fabriqués et vendus pour consommation au Canada, sauf disposition contraire des règlements.

Exception —
décision du
Conseil général

Coming into force

COMING INTO FORCE
4. This Act comes into force on a day to be fixed by order of the Governor

ENTRÉE EN VIGUEUR
4. La présente loi entre en vigueur à la date fixée par décret.

Entrée en
vigueur

in Council.

SCHEDULE 1

(Definition "pharmaceutical product" in section 21.02 and paragraph 21.03(1)(a))

abacavir (ABC)	tablet, 300 mg (as sulfate); oral solution, 100 mg (as sulfate)/5 mL
abacavir + lamivudine + zidovudine	tablet, 300 mg (as sulfate) + 150 mg + 300 mg
aciclovir	tablet, 200 mg; powder for injection, 250 mg (as sodium salt) in vial
amphotericin B	powder for injection, 50 mg in vial
amprenavir	capsule, 50 mg or 150 mg; oral solution, 15 mg/mL
azithromycin	capsule, 250 mg or 500 mg; suspension, 200 mg/5 mL
beclometasone	inhalation (aerosol), 50 micrograms per dose (dipropionate) or 250 micrograms (dipropionate) per dose
ceftazidime	powder for injection, 250 mg (as pentahydrate) in vial
ceftriaxone	powder for injection, 250 mg (as sodium salt) in vial
ciclosporin	capsule, 25 mg; concentrate for injection, 50 mg/mL in 1-mL ampoule (for organ transplantation)
ciprofloxacin	tablet, 250 mg (as hydrochloride)
ciprofloxacin	tablet, 250 mg or 500 mg
daunorubicin	powder for injection, 50 mg (as hydrochloride) in vial
delavirdine	tablet, 100 mg (as mesylate)
didanosine (ddI)	buffered chewable, dispersible tablet, 25 mg, 50 mg, 100 mg, 150 mg, 200 mg; buffered powder for oral solution, 100 mg, 167 mg, 250 mg, packets; unbuffered enteric coated capsule, 125 mg, 200 mg, 250 mg, 400 mg
diphtheria antitoxin	injection, 10 000 IU or 20 000 IU in vial
diphtheria vaccine	
doxorubicin	powder for injection, 10 mg or 50 mg (hydrochloride) in vial
efavirenz (EFV or EFZ)	capsule, 50 mg, 100 mg or 200 mg; oral solution, 150 mg/5 mL
eflornithine	injection, 200 mg (hydrochloride)/mL in 100-mL bottles
enalapril	tablet, 2.5 mg
erythromycin	capsule or tablet, 250 mg (as stearate or ethyl succinate); powder for oral suspension, 125 mg (as stearate or ethyl succinate); powder for injection, 500 mg (as lactobionate) in vial
etoposide	capsule, 100 mg; injection, 20 mg/mL in 5-mL ampoule
factor IX (complex coagulation factors II, VII, IX, X) concentrate	dried

hepatitis B vaccine	
ibuprofen	tablet, 200 mg or 400 mg
indinavir (IDV)	capsule, 200 mg, 333 mg or 400 mg (as sulfate)
insulin injection (soluble)	injection, 40 IU/mL in 10-mL vial or 100 IU/mL in 10-mL vial
intermediate-acting insulin	injection, 40 IU/mL in 10-mL vial; 100 IU/mL in 10-mL vial (as compound insulin zinc suspension or isophane insulin)
ivermectin	scored tablet, 3 mg or 6 mg

ANNEXE 1 (définition de « produit pharmaceutique » à l'article 12.02 et alinéa 21.03(1a))	
abacavir (ABC)	comprimé, 300 mg (sous forme de sulfate); solution buvable, 100 mg (sous forme de sulfate)/5 ml
abacavir + lamivudine + zidovudine	comprimé, 300 mg (sous forme de sulfate) + 150 mg + 300 mg
aciclovir	comprimé, 200 mg; poudre pour préparations injectables, 250 mg (sous forme de sel de sodium) en flacon
amphotéricine B	poudre pour préparations injectables, 50 mg en flacon
amprenavir	gélule, 50 mg ou 150 mg; solution buvable, 15 mg/ml
antitoxine diphtérique	solution injectable, 10 000 UI ou 20 000 UI en flacon
azithromycine	gélules, 250 mg ou 500 mg; suspension, 200 mg/5 ml
béclométasone	solution pour inhalation (aérosol), 50 microgrammes par dose (dipropionate) ou 250 microgrammes (dipropionate) par dose
carbonate de lithium	gélule ou comprimé, 300 mg
ceftazidime	poudre pour préparations injectables, 250 mg (sous forme de pentahydrate) en flacon
ceftriaxone	poudre pour préparations injectables, 250 mg (sous forme de sel de sodium) en flacon
chlorure de potassium	poudre pour solution
ciclosporine	gélule, 25 mg; concentré pour solution injectable, 50 mg/ml en ampoule de 1 ml (pour les transplantations d'organes)
ciprofloxacine	comprimé, 250 mg (sous forme de chlorhydrate)
ciprofloxacine	comprimé, 250 mg ou 500 mg
complexe de facteur IX (concentré des facteurs de coagulation II, VII, IX, X)	desséché
daunorubicine	poudre pour préparations injectables, 50 mg (sous forme de chlorhydrate) en flacon
delavirdine	comprimé, 100 mg (sous forme de mésilate)
didanosine (ddl)	comprimé à croquer, dispersible tamponné, 25 mg, 50 mg,

	100 mg, 150 mg, 200 mg; poudre tamponnée pour solution buvable, 100 mg, 167 mg, 250 mg en sachets; gélule gastro-résistante non tamponnée, 125 mg, 200 mg, 250 mg, 400 mg
doxorubicine	poudre pour préparations injectables, 10 mg ou 50 mg (chlorhydrate) en flacon
efavirenz (EFV ou EFZ)	gélule, 50 mg, 100 mg ou 200 mg; solution buvable, 150 mg/5 ml
éflornithine	solution injectable, 200 mg (chlorhydrate)/ml en flacon de 100 ml
énalapril	comprimé, 2,5 mg
érythromycine	gélule ou comprimé, 250 mg (sous forme de stéarate ou d'éthylsuccinate); poudre pour suspension buvable, 125 mg (sous forme de stéarate ou d'éthylsuccinate); poudre pour préparations injectables, 500 mg (sous forme de lactobionate) en flacon
étoposide	gélule, 100 mg; solution injectable, 20 mg/ml en ampoule de 5 ml
ibuprofène	comprimé, 200 mg ou 400 mg
indinavir (IDV)	gélule, 200 mg, 333 mg ou 400 mg (sous forme de sulfate)
insuline d'action intermédiaire	solution injectable, 40 UI/ml en flacon de 10 ml ou 100 UI/ml en flacon de 10 ml (sous forme d'un complexe d'insuline zinc en suspension ou d'insuline isophane)
insuline injectable (soluble)	solution injectable, 40 UI/ml en flacon de 10 ml ou 100 UI/ml en flacon de 10 ml
lamivudine (3TC)	tablet, 150 mg; oral solution 50 mg/5 mL
lamivudine + zidovudine	tablet, 150 mg + 300 mg
levodopa + carbidopa	tablet, 100 mg + 10 mg or 250 mg + 25 mg
levofloxacin	tablet, 250 mg or 500 mg
lithium carbonate	capsule or tablet, 300 mg
lopinavir + ritonavir (LPV/r)	capsule, 133.3 mg + 33.3 mg; oral solution, 400 mg + 100 mg/5 mL
metoclopramide	tablet, 10 mg (hydrochloride); injection, 5 mg (hydrochloride)/mL in 2-mL ampoule
metronidazole	tablet, 250 mg or 500 mg; injection, 500 mg in 100-mL vial; suppository, 500 mg or 1 g; oral suspension, 200 mg (as benzoate)/5 mL
morphine	injection, 10 mg in 1-mL ampoule (sulfate or hydrochloride); oral solution, 10 mg (hydrochloride or sulfate)/5 mL; tablet, 10 mg (sulfate)
nelfinavir (NFV)	tablet, 250 mg (as mesilate); oral powder, 50 mg/g
nevirapine (NVP)	tablet, 200 mg; oral suspension, 50 mg/5 mL
nifedipine	sustained release formulations, tablet, 10 mg

nitrofurantoin	tablet, 100 mg
ofloxacin	tablet, 200 mg or 400 mg
potassium chloride	powder for solution
ranitidine	tablet, 150 mg (as hydrochloride); oral solution, 75 mg/5 mL; injection, 25 mg/mL in 2-mL ampoule
ritonavir	capsule, 100 mg; oral solution, 400 mg/5 mL
salbutamol	tablet, 2 mg or 4 mg (as sulfate); inhalation (aerosol), 100 micrograms (as sulfate) per dose; syrup, 2 mg/5 mL; injection, 50 micrograms (as sulfate)/mL in 5-mL ampoule; respirator solution for use in nebulizers, 5 mg (as sulfate)/mL
saquinavir (SQV)	capsule, 200 mg
stavudine (d4T)	capsule, 15 mg, 20 mg, 30 mg or 40 mg; powder for oral solution, 5 mg/5 mL
testosterone	injection, 200 mg (enantate) in 1-mL ampoule
timolol	solution (eye drops), 0.25% or 0.5% (as maleate)
verapamil	tablet, 40 mg or 80 mg (hydrochloride); injection, 2.5 mg (hydrochloride)/mL in 2-mL ampoule
zalcitabine	tablet, 0.375 mg or 0.750 mg
zidovudine (ZDV or AZT)	tablet, 300 mg; capsule, 100 mg or 250 mg; oral solution or syrup, 50 mg/5 mL; solution for IV infusion injection, 10 mg/mL in 20-mL vial
ivermectine	comprimé sécable, 3 mg ou 6 mg
lamivudine (3TC)	comprimé, 150 mg; solution buvable, 50 mg/5 ml
lamivudine + zidovudine	comprimé, 150 mg + 300 mg
lévodopa + carbidopa	comprimé, 100 mg + 10 mg ou 250 mg + 25 mg
lévofloxacin	comprimé, 250 mg ou 500 mg
lopinavir + ritonavir (LPV/r)	gélule, 133,3 mg + 33,3 mg; solution buvable, 400 mg + 100 mg/5 ml
métoclopramide	comprimé, 10 mg (chlorhydrate); solution injectable, 5 mg (chlorhydrate)/ml en ampoule de 2 ml
métronidazole	comprimé, 250 mg ou 500 mg; solution injectable, 500 mg en flacon de 100 ml; suppositoire, 500 mg ou 1 g; suspension buvable, 200 mg (sous forme de benzoate)/5 ml
morphine	solution injectable, 10 mg (sulfate ou chlorhydrate) en ampoule de 1 ml; solution buvable, 10 mg (chlorhydrate ou sulfate)/5 ml; comprimé, 10 mg (sulfate)
nelfinavir (NFV)	comprimé, 250 mg (sous forme de mésilate); poudre pour administration orale, 50 mg/g
névirapine (NVP)	comprimé, 200 mg; suspension buvable, 50 mg/5 ml
nifédipine	formulations à libération prolongée, comprimé à 10 mg
nitrofurantoïne	comprimé, 100 mg

ofloxacin	comprimé, 200 mg ou 400 mg
ranitidine	comprimé, 150 mg (sous forme de chlorhydrate); solution buvable, 75 mg/5 ml; solution injectable, 25 mg/ml en ampoule de 2 ml
ritonavir	gélule, 100 mg; solution buvable, 400 mg/5 ml
salbutamol	comprimé, 2 mg ou 4 mg (sous forme de sulfate); solution pour inhalation (aérosol), 100 microgrammes (sous forme de sulfate) par dose; sirop, 2 mg (sous forme de sulfate)/5 ml; solution injectable, 50 microgrammes (sous forme de sulfate)/ml en ampoule de 5 ml; solution pour nébuliseur, 5 mg (sous forme de sulfate)/ml
saquinavir (SQV)	gélule, 200 mg
stavudine (d4T)	gélule, 15 mg, 20 mg, 30 mg ou 40 mg; poudre pour solution buvable, 5mg/5 ml
testostérone	solution injectable, 200 mg (énantate) en ampoule de 1 ml
timolol	solution (collyre), 0,25 % ou 0,5 % (sous forme de maléate)
vaccin antidiphtérique	
vaccin antihépatite B	
vérapamil	comprimé, 40 mg ou 80 mg (chlorhydrate); solution injectable, 2,5 mg (chlorhydrate)/ml en ampoule de 2 ml
zalcitabine	comprimé, 0,375 mg ou 0,750 mg
zidovudine (ZDV ou AZT)	comprimé, 300 mg; gélule, 100 mg ou 250 mg; solution buvable ou sirop, 50 mg/5 ml; solution pour perfusion intraveineuse, 10 mg/ml en flacon de 20 ml

SCHEDULE 2
(Paragraph 21.03(1)(b))

Afghanistan
Afghanistan
Angola
Angola
Bangladesh
Bangladesh
Benin
Bénin
Bhutan
Bhoutan
Burkina Faso
Burkina Faso
Burundi
Burundi
Cambodia
Cambodge

ANNEXE 2
(alinéa 21.03(1)(b))

Afghanistan
Afghanistan
Angola
Angola
Bangladesh
Bangladesh
Bénin
Benin
Bhoutan
Bhoutan
Burkina Faso
Burkina Faso
Burundi
Burundi
Cambodge
Cambodia

Cape Verde	Cap-Vert
<i>Cap-Vert</i>	<i>Cape Verde</i>
Central African Republic	Comores
<i>République centrafricaine</i>	<i>Comoros</i>
Chad	Djibouti
<i>Tchad</i>	<i>Djibouti</i>
Comoros	Érythrée
<i>Comores</i>	<i>Eritrea</i>
Democratic Republic of the Congo	Éthiopie
<i>République démocratique du Congo</i>	<i>Ethiopia</i>
Djibouti	Gambie
<i>Djibouti</i>	<i>Gambia</i>
Equatorial Guinea	Guinée
<i>Guinée équatoriale</i>	<i>Guinea</i>
Eritrea	Guinée-Bissau
<i>Érythrée</i>	<i>Guinea-Bissau</i>
Ethiopia	Guinée équatoriale
<i>Éthiopie</i>	<i>Equatorial Guinea</i>
Gambia	Haïti
<i>Gambie</i>	<i>Haiti</i>
Guinea	Îles Salomon
<i>Guinée</i>	<i>Solomon Islands</i>
Guinea-Bissau	Kiribati
<i>Guinée-Bissau</i>	<i>Kiribati</i>
Haiti	Lesotho
<i>Haïti</i>	<i>Lesotho</i>
Kiribati	Libéria
<i>Kiribati</i>	<i>Liberia</i>
Lao People's Democratic Republic	Madagascar
<i>République démocratique populaire lao</i>	<i>Madagascar</i>
Lesotho	Malawi
<i>Lesotho</i>	<i>Malawi</i>
Liberia	Maldives
<i>Libéria</i>	<i>Maldives</i>
Madagascar	Mali
<i>Madagascar</i>	<i>Mali</i>
Malawi	Mauritanie
<i>Malawi</i>	<i>Mauritania</i>
Maldives	Mozambique
<i>Maldives</i>	<i>Mozambique</i>
Mali	Myanmar
<i>Mali</i>	<i>Myanmar</i>
Mauritania	Népal
<i>Mauritanie</i>	<i>Nepal</i>
Mozambique	Niger
<i>Mozambique</i>	<i>Niger</i>

Myanmar
Myanmar
 Nepal
Népal
 Niger
Niger
 Rwanda
Rwanda
 Samoa
Samoa
 Sao Tome and Principe
Sao Tomé-et-Principe
 Senegal
Sénégal
 Sierra Leone
Sierra Leone
 Solomon Islands
Îles Salomon
 Somalia
Somalie
 Sudan
Soudan
 Togo
Togo
 Tuvalu
Tuvalu
 Uganda
Ouganda
 United Republic of Tanzania
République-Unie de Tanzanie
 Vanuatu
Vanuatu
 Yemen
Yémen
 Zambia
Zambie

Ouganda
Uganda
 République centrafricaine
Central African Republic
 République démocratique du Congo
Democratic Republic of the Congo
 République démocratique populaire lao
Lao People's Democratic Republic
 République-Unie de Tanzanie
United Republic of Tanzania
 Rwanda
Rwanda
 Samoa
Samoa
 Sao Tomé-et-Principe
Sao Tome and Principe
 Sénégal
Senegal
 Sierra Leone
Sierra Leone
 Somalie
Somalia
 Soudan
Sudan
 Tchad
Chad
 Togo
Togo
 Tuvalu
Tuvalu
 Vanuatu
Vanuatu
 Yémen
Yemen
 Zambie
Zambia

SCHEDULE 3
 (Paragraph 21.03(1)(c))

Albania
Albanie
 Antigua and Barbuda
Antigua-et-Barbuda
 Argentina
Argentine

ANNEXE 3
 (alinéa 21.03(1)c))

Afrique du Sud
South Africa
 Albanie
Albania
 Antigua-et-Barbuda
Antigua and Barbuda

Armenia
Arménie
 Bahrain, Kingdom of
Bahreïn, Royaume de
 Barbados
Barbade
 Belize
Belize
 Bolivia
Bolivie
 Botswana
Botswana
 Brazil
Brésil
 Brunei Darussalam
Brunéi Darussalam
 Bulgaria
Bulgarie
 Cameroon
Cameroun
 Chile
Chili
 China
Chine
 Colombia
Colombie
 Congo
Congo
 Costa Rica
Costa Rica
 Côte d'Ivoire
Côte d'Ivoire
 Croatia
Croatie
 Cuba
Cuba
 Dominica
Dominique
 Dominican Republic
République dominicaine
 Ecuador
Équateur
 Egypt
Égypte
 El Salvador
El Salvador

Argentine
Argentina
 Arménie
Armenia
 Bahreïn, Royaume de
Bahrain, Kingdom of
 Barbade
Barbados
 Belize
Belize
 Bolivie
Bolivia
 Botswana
Botswana
 Brésil
Brazil
 Brunéi Darussalam
Brunei Darussalam
 Bulgarie
Bulgaria
 Cameroun
Cameroon
 Chili
Chile
 Chine
China
 Colombie
Colombia
 Congo
Congo
 Costa Rica
Costa Rica
 Côte d'Ivoire
Côte d'Ivoire
 Croatie
Croatia
 Cuba
Cuba
 Dominique
Dominica
 Égypte
Egypt
 El Salvador
El Salvador
 Équateur
Ecuador

Fiji	Ex-République yougoslave de Macédoine
<i>Fidji</i>	<i>Former Yugoslav Republic of Macedonia</i>
Former Yugoslav Republic of Macedonia	Fidji
<i>Ex-République yougoslave de Macédoine</i>	<i>Fiji</i>
Gabon	Gabon
<i>Gabon</i>	<i>Gabon</i>
Georgia	Géorgie
<i>Géorgie</i>	<i>Georgia</i>
Ghana	Ghana
<i>Ghana</i>	<i>Ghana</i>
Grenada	Grenade
<i>Grenade</i>	<i>Grenada</i>
Guatemala	Guatemala
<i>Guatemala</i>	<i>Guatemala</i>
Guyana	Guyana
<i>Guyana</i>	<i>Guyana</i>
Honduras	Honduras
<i>Honduras</i>	<i>Honduras</i>
India	Inde
<i>Inde</i>	<i>India</i>
Indonesia	Indonésie
<i>Indonésie</i>	<i>Indonesia</i>
Jamaica	Jamaïque
<i>Jamaïque</i>	<i>Jamaica</i>
Jordan	Jordanie
<i>Jordanie</i>	<i>Jordan</i>
Kenya	Kenya
<i>Kenya</i>	<i>Kenya</i>
Kyrgyz Republic	Liechtenstein
<i>République kirghize</i>	<i>Liechtenstein</i>
Liechtenstein	Malaisie
<i>Liechtenstein</i>	<i>Malaysia</i>
Malaysia	Maroc
<i>Malaisie</i>	<i>Morocco</i>
Mauritius	Maurice
<i>Maurice</i>	<i>Mauritius</i>
Moldova	Moldova
<i>Moldova</i>	<i>Moldova</i>
Mongolia	Mongolie
<i>Mongolie</i>	<i>Mongolia</i>
Morocco	Namibie
<i>Maroc</i>	<i>Namibia</i>
Namibia	Nicaragua
<i>Namibie</i>	<i>Nicaragua</i>
Nicaragua	Nigéria
<i>Nicaragua</i>	<i>Nigeria</i>

Nigeria
Nigéria
 Oman
Oman
 Pakistan
Pakistan
 Panama
Panama
 Papua New Guinea
Papouasie-Nouvelle-Guinée
 Paraguay
Paraguay
 Peru
Pérou
 Philippines
Philippines
 Romania
Roumanie
 Saint Kitts and Nevis
Saint-Kitts-et-Nevis
 Saint Lucia
Sainte-Lucie
 Saint Vincent and the Grenadines
Saint-Vincent-et-les-Grenadines
 South Africa
Afrique du Sud
 Sri Lanka
Sri Lanka
 Suriname
Suriname
 Swaziland
Swaziland
 Thailand
Thaïlande
 Trinidad and Tobago
Trinité-et-Tobago
 Tunisia
Tunisie
 Uruguay
Uruguay
 Venezuela
Venezuela
 Zimbabwe
Zimbabwe

Oman
Oman
 Pakistan
Pakistan
 Panama
Panama
 Papouasie-Nouvelle-Guinée
Papua New Guinea
 Paraguay
Paraguay
 Pérou
Peru
 Philippines
Philippines
 République dominicaine
Dominican Republic
 République kirghize
Kyrgyz Republic
 Roumanie
Romania
 Sainte-Lucie
Saint Lucia
 Saint-Kitts-et-Nevis
Saint Kitts and Nevis
 Saint-Vincent-et-les-Grenadines
Saint Vincent and the Grenadines
 Sri Lanka
Sri Lanka
 Suriname
Suriname
 Swaziland
Swaziland
 Thaïlande
Thailand
 Trinité-et-Tobago
Trinidad and Tobago
 Tunisie
Tunisia
 Uruguay
Uruguay
 Venezuela
Venezuela
 Zimbabwe
Zimbabwe

SCHEDULE 4
(Paragraph 21.03(1)(d))

Cyprus
Chypre
Czech Republic
République tchèque
Estonia
Estonie
Hong Kong, China
Hong Kong, Chine
Hungary
Hongrie
Israel
Israël
Korea
Corée
Kuwait
Koweït
Latvia
Lettonie
Lithuania
Lituanie
Macao, China
Macao, Chine
Malta
Malte
Mexico
Mexique
Poland
Pologne
Qatar
Qatar
Singapore
Singapour
Slovak Republic
République slovaque
Slovenia
Slovénie
Chinese Taipei
Taipei chinois
Turkey
Turquie
United Arab Emirates
Émirats arabes unis

ANNEXE 4
(alinéa 21.03(1)d))

Chypre
Cyprus
Corée
Korea
Émirats arabes unis
United Arab Emirates
Estonie
Estonia
Hong Kong, Chine
Hong Kong, China
Hongrie
Hungary
Israël
Israel
Koweït
Kuwait
Lettonie
Latvia
Lituanie
Lithuania
Macao, Chine
Macao, China
Malte
Malta
Mexique
Mexico
Pologne
Poland
Qatar
Qatar
République slovaque
Slovak Republic
République tchèque
Czech Republic
Singapour
Singapore
Slovénie
Slovenia
Taipei chinois
Chinese Taipei
Turquie
Turkey

(Source : http://www.parl.gc.ca/37/3/parlbus/chambus/house/bills/government/C-9/C-9_2/C-9.html)

APPENDIX VITHE NETHERLANDS

Policy rules on issuing compulsory licences pursuant to WTO Decision WT/L/540 on the implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health, under section 57, subsection 1 of the Kingdom Act on Patents of 1995

The State Secretary for Economic Affairs, Having regard to the WTO Decision on the implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health (WT/L/540) and section 4:81 of the General Administrative Law Act,

Orders as follows:

Article 1

The following definitions shall apply for the purposes of these policy rules:

- a. the Minister: the Minister of Economic Affairs;
- b. the Act: the Kingdom Act on Patents of 1995;
- c. pharmaceutical product: any patented product, or product manufactured through a patented process, of the pharmaceutical sector needed to address public health problems, including active ingredients for the manufacture of these products and the diagnostic kits to use the products;
- d. compulsory licence: a licence as referred to in section 57, subsection 1 of the Patents Act 1995;
- e. the WTO Decision: the Decision of the General Council of the World Trade Organisation (WTO) on the implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health (WT/L/540);
- f. importing state: one of the least developed countries, or a WTO Member that has made a notification as referred to in article 2, paragraph (a) (ii) of the WTO Decision;
- g. group of states: a group of importing states, as well as organisations as referred to in article 6, paragraph (i) of the WTO Decision;
- h. order: a written order for a pharmaceutical manufacturer to manufacture a specific amount of a pharmaceutical product.

Article 2

1. In the interests of solving public health problems in an importing state or group of states, the Minister shall, upon receiving an application that satisfies the requirements of articles 3 and 4 of these policy rules, issue a compulsory licence as referred to in section 57, subsection 1 of the Patents Act 1995 for the pharmaceutical product that is needed to address the public health problems in question.

2. The compulsory licence shall at a minimum state the type and amount of the pharmaceutical product to which the compulsory licence issued for the purposes of the order applies.
3. The compulsory licence shall relate only to pharmaceutical products intended for the national market or markets of the importing state or group of states.

Article 3

1. The pharmaceutical manufacturer shall submit an application to the Minister for the issue of a compulsory licence.
2. The application shall be accompanied by an order addressed to the pharmaceutical manufacturer from an importing state, a group of states or a non-governmental organisation acting for one or more importing states.
3. If the pharmaceutical product to which the compulsory licence relates is intended for one of the least developed countries that is not a WTO Member, the application shall be accompanied by a declaration from that country affirming:
 - a. that the country does not have sufficient capacity to manufacture the pharmaceutical product and
 - b. what measures the country is taking to prevent trade diversion.
4. To prevent trade diversion of the pharmaceutical products to other states than the importing state, the pharmaceutical manufacturer shall take measures with regard to the packaging, colouring and/or shaping of the pharmaceutical products, provided these measures are feasible and do not have a significant impact on the price.
5. In its application, the pharmaceutical manufacturer shall state what measures, as referred to in paragraph 4, it has taken.
6. The compulsory licence shall contain the condition that, prior to shipping the pharmaceutical products to the importing state or group of states, the licensee shall post, on either its own website or the WTO webpage dedicated to that purpose, the measures that it has taken and the quantity and the characteristics, as referred to in paragraph 4, of the pharmaceutical products being shipped.

Article 4

If the order is placed by a WTO Member that is not one of the least developed countries, the application shall not be considered unless that Member meets the conditions referred to in article 2, paragraph (a) (ii) of the WTO Decision.

Article 5

Taking into account the economic value of the order to the importing state, the Minister shall determine adequate remuneration to be paid by the licensee to the patent holder as compensation for the compulsory licence.

Article 6

A decision by the Minister on issuing a licence, as referred to in article 2, shall state whether the lodging of an objection or an application for review will suspend implementation of the decision.

Article 7

These policy rules shall enter into force on the second day after the date of the Government Gazette in which they appear.

These policy rules will be published in the Government Gazette with the explanatory notes.

The Hague, 17 December 2004

The State Secretary for Economic Affairs

EXPLANATORY NOTES

I. GENERAL

These policy rules execute the Decision of the General Council of the World Trade Organisation (WTO) on the implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health (WT/L/540) ("the WTO Decision"). The WTO Decision makes it possible to issue compulsory licences for the export of pharmaceutical products to states where public health problems are grave if those states do not have sufficient capacity to manufacture those pharmaceutical products themselves.

It was decided that the WTO Decision would be implemented by means of policy rules explaining the nature of the Minister of Economic Affairs' general authority to issue compulsory licences pursuant to section 57, subsection 1 of the Patents Act 1995. These policy rules are subject to articles 4:81 to 4:84 of the General Administrative Law Act.

Some countries cannot solve their public health problems because they do not have the capacity to manufacture pharmaceutical products. For various reasons, it can also be difficult to purchase these pharmaceutical products. For instance, they may be covered by one or more patents. As a result, the price may be too high for developing countries to buy sufficient quantities from either the patent holder or a licensee. In addition, the patent holder's available manufacturing capacities may be insufficient to meet the demand.

Manufacturers of generic pharmaceutical products may not market cheaper copies of patented products unless the patent has expired or a licence for that purpose has been issued to them. If the patent holder will not voluntarily issue such a licence, the Minister of Economic Affairs ("the Minister") may issue a compulsory licence pursuant to section 57, subsection 1 of the Patents Act 1995. That subsection empowers him to issue compulsory licences if, in his opinion, it is in the public interest to do so.

The Minister must exercise this authority in accordance with article 31 of the TRIPS Convention, which contains conditions for the issue of such compulsory licences. Article 31, paragraph (f) of the TRIPS Convention states that compulsory licences shall be authorised predominantly in order to supply patented products to a domestic market. Article 31, paragraph (h) states that the patent holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorisation. The value of the licence that is considered is that in the patent holder's country, which is often higher than that in the importing country. The obligations set out in article 31, paragraphs (f) and (h) make it impossible to issue compulsory licences with the aim of increasing the availability of sufficient affordable pharmaceutical products for developing countries that do not have the capacity to manufacture generic versions. The WTO Decision attempts to bring this situation to an end by stipulating that, if a compulsory licence is issued in line with its provisions, article 31, paragraphs (f) and (h) of the TRIPS Convention shall not apply. Accordingly, the reference to the public interest in section 57, subsection 1 of the Patents Act 1995 may be interpreted as including the addressing of a public health problem in another WTO Member or in one of the least developed countries.

The WTO Decision creates a system for issuing compulsory licences aimed at solving the public health problem. The only purpose for which importing states or groups of states may use the imported pharmaceutical products is to address their own public health problems. The policy rules are intended to help alleviate public health problems in countries that may import cheap pharmaceutical products on the basis of the WTO decision on this matter of 30 August 2003. The solution offered by this arrangement may not be used improperly in pursuit of industrial or commercial ends.

The WTO Decision also allows WTO Members that are not among the least developed countries to apply to import generic pharmaceutical products if they have made a notification as referred to in article 2, paragraph (a) (ii). However, a number of Members have declared that they will not make use of the system as importing Members; this includes all the EU member states, Australia, Canada, Iceland, Japan, New Zealand, Norway, Switzerland and the United States.

The WTO Decision provides for waivers of the obligations set out in article 31, paragraphs (f) and (h) of the TRIPS Convention in the interest of public health in WTO Members. These waivers do not formally apply to non-WTO Members. However, it was decided that the policy rules would also be made applicable to non-WTO Members that are among the least developed countries, because they too face major public health problems and have insufficient manufacturing capacities.

On application by a pharmaceutical manufacturer who has received an order from an importing state or group of states, a compulsory licence is issued by the exporting state if the conditions for issue have been met.

These policy rules were drafted prior to the presentation of the European Commission Regulation on this topic, which is now in preparation and will be presented to the Council by the Commission to promote uniform national implementation throughout the European Union. At such time as this Regulation enters into force, Dutch legislation will be amended to conform with it as needed.

II. INDIVIDUAL ARTICLES

Article 1

Paragraph (c) adopts the definition of 'pharmaceutical product' from the WTO Decision, in which the term covers not only medicines but also the diagnostic kits needed to use the medicines.

Article 2

Compulsory licenses exhaustively specify the scope of the waiver granted; they are intended solely for the manufacture of the pharmaceutical products mentioned in the application. The scope of the compulsory licence must be commensurate with the public health problems to be solved.

Under section 57, subsection 1 of the Patents Act 1995, the Minister must make certain that the patent holder is unwilling to issue a voluntary licence before issuing a compulsory licence. In urgent cases, the section in question allows the Minister to refrain from investigating whether the patent holder is willing to issue a licence voluntarily.

In forming a view on the existence of a public health problem, the Minister will follow the notification arrangements set out in the WTO Decision or, with regard to least developed countries that are not WTO Members, the arrangements described in article 3, paragraph 3 of these policy rules.

The foregoing does not affect the Minister's obligation under section 4:84 of the General Administrative Law Act to ascertain, when giving a decision, whether this decision may have an impact on one or more interested parties that due to exceptional circumstances would be out of proportion to the aims of these policy rules.

Article 3

The pharmaceutical products manufactured under the compulsory licence may only be used as part of the solution to the public health problems of the importing country. It is therefore important for the pharmaceutical products not to be re-exported from the importing country. The pharmaceutical manufacturer submits an application to the

Minister of Economic Affairs. These applications are subject to the General Administrative Law Act, especially sections 4:2 and 4:3. Under these sections and these policy rules, the applicant is required to state at a minimum the name and quantity of the pharmaceutical product that it wishes to manufacture and the patent by which the product is covered. If an application is not accompanied by one of the documents referred to in article 3, paragraph 2, such as the order, section 4:5 of the General Administrative Law Act shall apply, which requires the administrative authority to give the applicant the opportunity to supplement its application within a period set by the administrative authority*.

A pharmaceutical manufacturer who applies for a compulsory licence must state in the application what measures it will take to prevent trade diversion of the pharmaceutical products that it manufactures and exports under the compulsory licence. At a minimum, it must state what measures it will take with regard to the packaging, colouring or shaping of the pharmaceutical products. If the manufacturer does not intend to take these measures because they are not feasible or have a significant impact on the price, it must explain why this is the case.

If it comes to light that the pharmaceutical manufacturer is misusing the compulsory licence and hence is partly or wholly responsible for the trade diversion of the pharmaceutical products that it manufactured and exported, criminal charges may be brought against it.

Article 4

If a country wishes to make use of the system established by the WTO Decision, it must make a notification to the Council for TRIPS. If the importing Member is not among the least developed countries, the compulsory licence will only be issued if that Member has notified the WTO, through the proper procedure, that it intends to use the system.

If such notification has been made, it will be assumed that the Member using the system established by the WTO Decision meets the applicable conditions.

Article 5

Under normal circumstances, the remuneration that the licensee pays to the patent holder must be commensurate with the economic value of the authorisation in ordinary trade. In the present case, the remuneration will be based on the value of the pharmaceutical products in the importing country. If price and income levels are lower in that country than in the Netherlands, that fact will play a leading role in the calculation of the remuneration owed. As a result, the pharmaceutical products should be affordable to everyone in the importing country.

Article 6

Section 57, subsection 1 of the Patents Act 1995 stipulates that objections against and applications for review of a decision to issue a compulsory licence shall suspend implementation of the decision, unless that would be inappropriate in view of the urgency of the case. Such cases are likely to be regarded as urgent, given the gravity of the public health problems in the countries for which the pharmaceutical products to be exported are intended. For that reason, the Minister will always state in his decision whether or not he will allow objections and applications for review to suspend implementation.

The State Secretary for Economic Affairs

(Source : www.cptech.org/ip/health/cl/netherlands-export-rules.html)

APPENDIX VIINORWAYRegulations amending the Patent Regulations (in accordance with the decision of the WTO General Council of 30 August 2003, Paragraphs 1(b) and 2(a))

Pursuant to sections 49 and 69 of the Act of 15 December 1967 No. 9 relating to patents, the Ministry of Justice and the Police laid down the following regulations by Royal Decree of 14 May 2004:

The Regulations of 20 December 1996 No. 1162, which have been issued pursuant to the Patents Act, shall be amended as follows:

New section 107 shall read as follows:

Section 107. When the requirements set out in section 108 have been complied with, a producer of pharmaceutical products in Norway shall be granted on application a compulsory licence pursuant to section 47 of the Patents Act to manufacture pharmaceutical products for export to an eligible importing State that has requested the producer to supply the products. For the purpose of these regulations, an eligible importing State or customs territory is one that:

1. at the time in question has been designated by the UN as a least developed country or customs territory, or that has insufficient manufacturing capacity in accordance with the Annex to the decision of the WTO General Council of 30 August 2003 (the General Council Decision), and
2. has made a notification to the Council for TRIPS in accordance with the General Council Decision, paragraphs 1(b) and 2(a).

States that are not party to the WTO Agreement shall make the notification referred to in the first paragraph (2) above to the Norwegian Ministry of Foreign Affairs.

New section 108 shall read as follows:

Section 108. A compulsory licence may only be granted pursuant to section 107 if

1. the producer has tried to obtain a licence by agreement in Norway insofar as this is required pursuant to section 49, first paragraph, of the Patents Act,
2. the product is covered by paragraph 1(a) of the General Council Decision,
3. the product is only to be produced for export to the eligible importing State in order to cover the said State's current need for the product for health purposes, as described in the notification mentioned in section 107, and
4. the invention is not protected by a patent in the eligible importing State or the eligible importing State has granted or has undertaken proceedings to obtain a

compulsory licence pursuant to Article 31 of the Agreement of 15 April 1994 on Trade-Related Aspects of Intellectual Property Rights (the TRIPS Agreement) and the General Council Decision.

When assessing what are reasonable commercial terms and conditions pursuant to section 49, first paragraph, of the Patents Act, and when determining the remuneration pursuant to section 50, second paragraph, of the Patents Act, account shall be taken of the economic value to the importing State of the use of the invention.

More detailed requirements for granting a compulsory licence may be imposed in the decision to grant such a licence, cf. section 50, first paragraph, of the Patents Act. These shall include the following requirements

1. the packaging and container shall be distinct from those of products being offered for sale in Norway or in another state by the patent-holder himself or with his consent,
2. the products shall be labelled so as to clearly indicate that the pharmaceutical product has been manufactured under compulsory licence in Norway for export to a specified importing state in accordance with the General Council Decision, and
3. the manufacture and export shall cease if the licence-holder learns the products are being used to an appreciable degree for purposes that are not in accordance with the conditions for granting the licence, cf. first paragraph (3).

New section 109 shall read as follows:

Section 109. The competent court or the Competition Authority shall make a notification to the Council for TRIPS concerning the compulsory licence in accordance with the General Council Decision, paragraph 2(c). States that are not party to the WTO Agreement shall make a notification to the Norwegian Ministry of Foreign Affairs.

The holder of a compulsory licence shall post information on its website in accordance with the General Council Decision, paragraph 2(b)(iii).

These regulations enter into force on 1 June 2004.

EXPLANATORY NOTES (extract)

Regulations amending the Patent Regulations (implementation of the Decision of the WTO General Council of 30 August 2003, paragraphs 1(b) and 2(a))

8. Comments on the Individual Provisions of the Regulations

Section 107

The *first paragraph* sets out that under certain specified conditions a pharmaceutical company in Norway is to be granted a compulsory licence to use a patent-protected invention with a view to manufacturing pharmaceutical products for export to another State. Thus producers that apply for a compulsory licence have a legal right to such a licence if the conditions have been fulfilled. This ensures greater predictability than if compulsory licences were to be granted on a discretionary basis, and reduces the risk inherent in starting negotiations on supplying products before a compulsory licence has been granted in Norway. As long as the importing State's request to import the pharmaceutical product is based on public health considerations and falls within the scope of the General Council Decision and the provisions of the TRIPS Agreement, the requirement of important public interests must be considered to have been met, cf. section 47 of the Patents Act. The Norwegian authorities should thus not evaluate independently whether such important public interests are involved, cf. the comments on section 108, first paragraph, item 3, below.

A compulsory licence may only be granted if the pharmaceutical products in question are to be produced for export to an "eligible importing State." The State must have requested the producer to supply the pharmaceutical products, but a final agreement is not required.

The provision does not prevent the producer from exporting to more than one State as long as the conditions for compulsory licence have been met in each case.

For the purpose of the regulations, an eligible importing State is any State that, at the time when the application for a compulsory licence is submitted, is designated by the UN as a least developed country, or that has insufficient manufacturing capacity in accordance with the Annex to the General Council Decision. The State must also have made a notification to the Council for TRIPS in accordance with paragraph 1(b) and paragraph 2(a) of the General Council Decision. The information in the notification is described under section 3.3 above. A customs territory may also be an "eligible importing State," since separate customs territories have independent rights under the WTO Agreement.

It is also proposed that States that are not Members of the WTO should be given the opportunity to conclude agreements on the import of pharmaceutical products manufactured under compulsory licence in Norway on the same terms as Members of the WTO, cf. section 107, *second paragraph*, of the draft regulations. In such cases notification concerning the information contained in the General Council Decision must be made to the Ministry of Foreign Affairs.

Section 108

The *first paragraph* sets out the remaining conditions for granting a compulsory licence for exports to an eligible importing State.

One condition for obtaining a compulsory licence is that the producer has first unsuccessfully tried to obtain a voluntary licence, cf. Article 31(b) of the TRIPS Agreement. This is not necessary in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. The provision set out in section 49, first paragraph, of the Patents Act (amended by Act of 19 December 2003 No. 127) is based on this, cf. Proposition No. 86 (2002-2003) to the Odelsting, p. 80, first column. The General Council Decision does not make an exception from this provision of the TRIPS Agreement.

Pharmaceutical products that are manufactured under this system will probably normally be subject to non-commercial use under the auspices of the public authorities of the importing State. It is possible, however, that commercial health institutions in the importing State will also be given access to the products. It cannot be assumed, therefore, that it will never be necessary to first try to obtain a voluntary licence, and this must be evaluated on a case-to-case basis. Often the most reasonable way to proceed would at any rate be to begin by negotiating with the right holder.

Thus, according to the *first paragraph, item 1*, of section 108, the producer must first have tried to obtain a licence on reasonable commercial terms and conditions by agreement, insofar as this is required pursuant to section 49, first paragraph, of the Patents Act. In considering what are “reasonable commercial terms and conditions,” account must be taken of the economic value that the use of the invention represents for the importing State, cf. section 108, second paragraph. If the right holder demands a fee that cannot be regarded as reasonable, the condition for a compulsory licence pursuant to the first paragraph, item 1, is fulfilled.

A compulsory licence may only be granted if the pharmaceutical product in question is covered by paragraph 1(a) of the General Council Decision, see *first paragraph, item 2*.

Another condition is that the product must be produced only for export to the eligible importing State in order to satisfy the State’s current public health needs, as set out in the notification in section 107, see *first paragraph, item 3*, of the draft of section 108. A compulsory licence must be limited to such cases. The provision is based on paragraph 2(a) and (b) of the General Council Decision.

The fact that it is the importing State’s “current public health needs” that are to be met means that the Norwegian authorities should normally take account of the public health needs specified in the notification as long as it is made clear that these needs are consistent with the situation at the time when the request for a compulsory licence is submitted. The importing State’s own assessment on this point should not be reviewed by the Norwegian authorities unless there are specific indications that the situation has been inaccurately described, for example if the importing State’s real intention is that the product should be used for industrial rather than public health purposes. However, the compulsory licence must be within the limits of the notification to the Council for TRIPS. The notification by the importing State will therefore indicate the scope of the licence.

Another condition is that the invention must not be protected by a patent in the eligible importing State, or that the said State has granted or has undertaken proceedings to obtain a compulsory licence pursuant to Article 31 of the TRIPS Agreement and the General Council Decision, for example by filing a writ of summons. This condition is specified in section 108, *first paragraph, item 4*, which is based on paragraph 2(a)(iii) of the General Council Decision.

The draft regulations do not impose specific standards of quality that the product must satisfy, for example whether the product needs to have been approved for marketing in Norway or another EEA country. Thus it is the quality requirements in the importing State that will determine which pharmaceutical products may be manufactured in Norway for export under a compulsory licence. However, the pharmaceutical products must be manufactured in accordance with Norwegian statutory requirements concerning the manufacturing process.

The *second paragraph* sets out that when assessing what are reasonable commercial terms and conditions pursuant to section 49, first paragraph, of the Patents Act., and when determining the remuneration to the right holder pursuant to section 50, second paragraph, of the Act, account is to be taken of the economic value to the importing State of the use of the invention. The provision is based on paragraph 3 of the General Council Decision, which defines more closely the provision of Article 31(h) of the TRIPS Agreement, which states that the remuneration is to take account of “the economic value of the authorization.”

The fact that market conditions in the importing State are to be taken into consideration often means that the remuneration is fixed at a relatively low level.

If pharmaceutical products are manufactured or sold in Norway under compulsory licence in conflict with the licensing conditions, the patent will in principle have been violated. In such cases the patent holder will be able to invoke the general penal provisions of the Patent Act. It is important that the patent holder is also protected against unauthorized use of the invention in the importing State, for example if it is exported to an unauthorised State. The decision to grant a compulsory licence must include conditions to guard against such unauthorised use, *cf. third paragraph*. Furthermore, the labeling and container must be distinct from those of products being offered for sale in Norway or in another state by the patent holder himself or with his consent, *cf. third paragraph, item 1*. The products must also be labeled so as to clearly indicate that the pharmaceutical product has been manufactured under compulsory licence in Norway for export to a specified importing state in accordance with the General Council Decision, *cf. third paragraph, item 2*. These provisions are based on paragraph 2(b)(ii) of the General Council Decision. A further requirement is that the manufacture and export of the product are to cease if the licence holder learns that the products are being used to an appreciable degree for purposes that are not in accordance with the conditions for granting the licence. This provision is intended to take account of the comments by the Bar Association, the Ministry of Health, the Association of Pharmaceutical Manufacturers and the Intellectual Property Law Association.

The expiry of the compulsory licence is otherwise covered by the general provisions of the Patent Act. Special reference is made to section 50, second paragraph, of the Patent Act, which gives the competent court the right to cancel the licence if circumstances should change considerably.

Section 109

The *first paragraph* has been included in response to a proposal by the Association of Pharmaceutical Manufacturers. The provision prescribes that the competent court or the Competition Authority is to make a notification to the Council for TRIPS concerning the compulsory licence in accordance with the General Council Decision, paragraph 2©.

The *second paragraph* obliges the recipient of a compulsory licence to post certain information on its website. This information consists of the quantities being manufactured, the name of the importing State and distinguishing features of the packaging, see paragraph 2(b)(iii) of the General Council Decision.

(Source: www.dep.mo/ud/engelsk/p2500832)

APPENDIX VIIIWTOLeast-developed countries

The WTO recognizes as least-developed countries (LDCs) those countries which have been designated as such by the United Nations. There are currently 50 least-developed countries on the UN list, 32 of which to date have become WTO members.

These are:

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

Eight additional least-developed countries are in the process of accession to the WTO. They are: Bhutan, Cape Verde, Ethiopia, Laos, Samoa, Sudan, Vanuatu and Yemen.

Furthermore, Equatorial Guinea and Sao Tome & Principe are WTO Observers.

There are no WTO definitions of “developed” or “developing” countries. Developing countries in the WTO are designated on the basis of self-selection although this is not necessarily automatically accepted in all WTO bodies.

(Source: www.wto.org/english/thewto_e/whatis_e/tif_e/org7_e.htm. Page accessed 10/15/2004)