Bill C-9: An Act To Amend The Patent Act and The Food And Drugs Act – A Model For The World But Is It Workable?

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Canada may be the first country[1] to pass legislation to allow the export of generic versions of patented medicines to developing countries, in response to the 30 August Decision of the World Trade Organization (WTO). Bill C-9, the *Jean Chrétien Pledge to Africa* ("JCPA"), will likely come into force before the end of the year.[2]

Unfortunately, the JCPA appears to be a mere public relations exercise. It is not a workable scheme for ensuring low-cost drugs are exported from Canada to Africa or other developing nations.

I represented the generic industry as counsel throughout the consultations with government on Bill C-9, in the fall of 2003 and spring of 2004. Although the federal government expressed strong interest in passing legislation allow the export of low-cost drugs to needy countries as quickly as possible, it was also clear the government intended to include so many provisions to protect the rights of patentees that it was unlikely generic manufactures would ever use the scheme.

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[1] Similar measures are under discussion elsewhere. For example, the European Commission released "Proposal for a Regulation of the European Parliament and of the Council on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems" on October 29, 2004. EU Trade Commissioner Pascal Lamy said in an accompanying press release that he hoped the proposal "could be taken forward quickly by the EU Member States and the European Parliament."

[2] Bill C-9, *An Act to Amend the Patent Act and the Food and Drugs Act (The Jean Chrétien Pledge to Africa)* received third reading in the House of Commons on May 4, third reading in the Senate on May 13, and Royal Assent on May 14, 2004. The Act comes into force by a day to be fixed by Order of the Governor in Council. Draft regulations were published in the *Canada Gazette, Part 1*, October 2, 2004, p. 2748 with a 75 day consultation period within which interested parties may respond.

The JCPA imposes considerable risks and costs on anyone seeking to export low-cost drugs to needy countries. For example, the patentee has the benefit of three separate, differently-worded rights under the JCPA to start litigation against the generic manufacturer, each in addition to the normal right to enforce patents under the *Patent Act*.

Furthermore, a short four year time limit is put on the length of the compulsory license that makes it uneconomic to get one.

It must be kept in mind that formulating and obtaining regulatory approval for a genertic version of a drug needed in a developing country could easily take a generic manufacturer two years or more. Generic manufacturer are unlikely to recoup let alone earn a return on the cost because prices will be generally established by international tender, and will therefore be low. To win a contract to supply such drugs, Canada's generic manufacturers would likely have to compete, for example, against generic manufacturers in India with much lower regulatory and labour costs.

The JCPA encourages generic manufacturers to, in effect, make charitable donation to the third world, a praiseworthy goal. But then the legislation penalizes generic manufacturers for doing just that.

An analogy would be a scheme imposing a heavy administrative burden rife with unknown legal and financial risks on anyone who donated food to the food bank. Such a scheme would be unlikely to encourage food bank donations.

Many of the more onerous provision in the JCPA from the point of view of generic manufacturers are not required under the August 30, 2003 Decision of the World Trade Organization, the international joint statement that authorizes such legislation.

Before going further, it is necessary to describe the background to the JCPA and the bill itself.

Background to the JCPA

There is great need for low-cost medicines in the developing world. For example, more than 20 million people have died from the global AIDS pandemic. As of the end of 2003, 38 million people were living with HIV/AIDS worldwide, 25 million of them in Sub-Saharan Africa. Only about 7% of the people in developing countries who need anti-retroviral drugs have access to them.[3] The prevalence of HIV/AIDS varies widely from one African country to another, but is as high as 35% of the population in Swazliland and Botswana.[4]

Many nations most affected by the AIDS and other epidemics do not have the domestic manufacturing capabilities to produce their own low-cost versions of the necessary medicines.

Doha Declaration

In light of this problem, the Doha Declaration[5] was issued by the World Trade Organization (WTO) on November 17, 2001. Paragraph 6 stated:

> 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.

[3] 2004 Report on the Global AIDS Epidemic, Joint United Nations Programme on HIV/AIDS, p. 3
[4] Ibid, p. 6.
[5] Declaration of the TRIPS agreement and public health," November 14, 2001

The Doha Declaration acknowledged a short-coming of the TRIPS Agreement, enacted by international agreement in 1994. TRIPS sets out standards which the intellectual property laws of all member companies must meet.

Under TRIPS, Article 31, a member country can issue a compulsory license particularly in the event of a health crisis, but only to supply its own domestic markets. Article 31(f) states "any such use [under a compulsory license] shall be authorized predominantly *for the supply of the domestic market* of the Member authorizing such use."

TRIPS also has another problematic provision. If a compulsory license is issued, Article 31(h) of TRIPS requires that "the right holder [patentee] shall be paid adequate remuneration in the circumstances, taking into account the economic value of the authorization." In other words, even poor countries in the grip of a health disaster, must ensure that its law requires that "adequate remuneration" is paid to the patentee if a compulsory license to a medicine is issued.

In short, TRIPS does not permit a Member country to pass a compulsory license to address a health crisis in another country. Therefore poor countries without pharmaceutical manufacturing facilities cannot get drugs, because rich companies cannot issue compulsory licences that would allow drugs to be manufactured for export to poor countries.

August 30 Decision

After lengthy negotiations, the WTO followed up with its August 30, 2003 Decision,[6] a copy of which is attached as Appendix "A." In effect, the 30 August Decision waives Articles 31(f) and (h) of TRIPS, so that members countries may amend their legislation to

[6] Council for TRIPS: Decision of 30 August 2003 WT/L/540 "Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health." The 30 August Decision was released with an accompanying statement of the same date "The General Council Chairperson's statement."

permit compulsory licences, in certain circumstances, provided certain requirements are met by the member country.

The main points in the 30 August Decision are:

- The obligations of an exporting member (such as Canada) under Article 31(f) shall be waived with respect to a compulsory licence allowing export of pharmaceutical products to an "eligible importing member."[7]

- The "eligible importing member" must have made a "notification" to the Council for TRIPS that specifies (i) the drugs it needs (ii) that it has insufficient or no manufacturing capacity in the pharmaceutical section, and (iii) that, if the drug is patented in its territory that it intends to issue a compulsory license.[8]

- The compulsory licence must contain three conditions: (i) only the "amount necessary" can be manufactured, and all of it must be exported, (ii) products must be "clearly identified" as being produced under the Decision through specific labeling or colouring/shaping of the products themselves, provided this is feasible, and has no significant impact on price, and (iii) the licensee must have a website describing the quantities of drug shipped, and describing the "distinguishing features" of the products shipped

- The "reasonable remuneration" in Article 31(h) is waived in the importing country, although it still must be paid in the exporting country.[9]

- The importing country must take "reasonable measures" to prevent diversion.[10]

[7] 30 August Decision, paragraph 2.
[8] Ibid, paragraph 2(a)
[9] Ibid, paragraph 3
[10] Ibid, paragraph 4.

- Members shall ensure the availability of "effective legal means" to prevent importation of products produced under the scheme into their territories, if the importation is inconsistent with the Decision.[11]

Bill C-91

Canada began working on implementing legislation in response to the 30 August Decision almost immediately. It became apparent during consultations in the fall of 2003 that every official in Ottawa with any involvement in pharmaceutical matters had been told to treat the project as a top priority, and to get legislation ready in response to the 30 August Decision as soon as possible.

The legislation, originally known as Bill C-56, went through several drafts. The name JCPA was added at third reading. The relevant provisions of the JCPA, as given royal assent, are as follows:

Schedule 1 list of drugs

A list of "pharmaceutical products", Schedule 1, sets out the drugs to which the scheme applies. It includes drugs for AIDS, malaria, tuberculosis and other diseases.

Schedule 1 can be changed only by an order of the Governor in Council, that is, the federal cabinet.[12] This is considerably more cumbersome than what appeared to be contemplated by the 30 August Decision, which provides merely that needy countries must do no more than provide a "notification" to TRIPS Council naming a drug they need.

[11] Ibid, paragraph 5.
[12] Section 21.03.

Canada could have merely said that any drug for which a notification has been provided to TRIPS Council was within the scheme.[13] This is just one of the ways in which the Canadian government has made it domestic legislation considerably more complex and less flexible than what seemed to be contemplated by the 30 August Decision. Medicines Sans Frontiers, a group of doctors with an interest in the developing world, strongly opposed the omission of certain retroviral cocktails from Schedule 1. They objected strongly as well to existence of a schedule, which will require extensive and costly lobbying to amend if, for example, news drugs become available for diseases such as AIDS/HIV.

There seems to have been lobbying to get drugs taken off Schedule 1. Clarithromycin, an antibiotic, for example, mysteriously disappeared from Schedule 1 shortly before Bill C-9 received royal assent.

Eligible Countries

There are also schedules of countries under the scheme, in three categories: Schedule 2: "least developed countries," Schedule 3: countries that have advised WTO they wish to import drugs under the scheme because they lack adequate manufacturing facilities, and Schedule 4 , countries that have informed WTO they may use the scheme, but only in a specific emergency.[14] Like Schedule 1, these schedules also can be changed only by an order of Cabinet.

The application for a license

Section 21.04 deals with the form of an application to the Commissioner of Patents to obtain a compulsory license. Information is required such as the drug, the amount, the

[13] As in the EU proposal which does not contain a schedule of drugs, see Article 2 and Article 5.
[14] Section 21.03.

name of the patentee, the importing country, and the person or entity in the government of the important country or the "person or entity permitted by the government of the importing country."

The Commissioner of Patent shall authorize the use of the patented invention (i.e. issue a compulsory license) if various requirements are met.

Health and safety approval

The applicant must have satisfied the Minister of Health that the drug meets the requirements of the *Food and Drugs Act*.[15] That is, the level of regulatory scrutiny applied to drugs under the scheme will be the same as for drugs approved for sale in Canada.

Marking, embossing, labeling and packaging

There are also accompanying regulations requiring the actual dosage form to be manufactured "in a manner that distinguishes it from the version of the pharmaceutical product sold in Canada."[16]

The Regulations require that the product bears the mark "XCL", and that the colour of the drug must be "significantly different" from the colour of the version sold in Canada. The product label must set out specified wording: "FOR EXPORT UNDER THE GENERAL COUNCIL DECISION, NOT FOR SALE IN CANADA,"[17] and display an export tracking number, assigned by the Minister of Health.

[15] Section 21.04 (3)(b).
[16] Section 21.04(3)(a).
[17] Draft "Regulations Amending the Food and Drug Regulations (1402-Drugs for Developing Countries)" *Canada Gazette, Part 1*, p. 2756, section C.07.008.

Generic manufacturers point out that generic drugs in Canada have the same size, shape and colour as the brand product. Generic drugs are distinguished from the brand in that the abbreviated name of the generic manufacturer may be embossed on the dosage form, e.g. “APO” or “NOVO”, and the generic drugs are packaged in such a way that the manufacturer is identified. This should be enough to ensure generic drugs can be distinguished from the brand product, in the event that the drugs are diverted from the exporting country to some other market.

The requirement under the scheme that drugs be a different colour from the brand increases the cost of producing generic drugs for export, because such products must look different from the generic’s own version of the product for the domestic market, after patent expiry. This is one more disincentive for generic manufacturers to participate in the scheme.

There is no express requirement in the 30 August decision that the drug exported under license be a different colour, merely that it be identified by special packaging *or* special colouring.

Must ask patentee for license

The Minister must also be satisfied that the applicant has asked for, but failed to obtain a license from the patentee “on reasonable terms and conditions and that such efforts have not been successful.”[18] This is in response to Article 31(b) of TRIPS, not waived by the 30 August Decision, which requires that, before the compulsory license is issued, the proposed user must have “made efforts to obtain authorization from the right holder on reasonable terms and conditions.”

Patent situation in importing country etc.

[18] Bill C-9,section 21.04(3)(c)

Other material must be filed with the application which is not mentioned in the 30 August Decision, nor in TRIPS, and which does not appear to be necessary. For example, the applicant must file a statutory declaration as to what relevant patents, if any, exist in the importing county, and information showing the importing country intends to issue a compulsory license for them. The applicant must also file a copy of the declaration that the importing country has filed with the TRIPS council saying that it has insufficient manufacturing capacity. Thus the Commissioner of Patents appears to have been put in a position where he must assess the patent situation in a foreign country, and whether that country is or is not in compliance with its international obligations under TRIPS.

Website

There is also a requirement in JCPA that an application for a compulsory license be posted on the CIPO website within 7 days of receipt.[19] (It will soon be possible to test whether my prediction that the scheme will not be used.)

Notice to patentee at various times

Fifteen days after the authorization (i.e. compulsory license) is granted, or the day on which the agreement with the supplier is entered into, the license-holder must send a copy of its agreement with its customer to the patentee, along with a statutory declaration as to the total monetary amount of the agreement in Canadian currency and the number of units to be sold.[20]

[19] Section 21.06(4).
[20] Section 21.16 (1).

Fifteen days before the material is shipped, the compulsory license holder must send a notice to the patentee, importing country and purchaser specifying "every known party in the distribution chain from Canada to the final country of import."[21]

Royalty to patentee

A royalty must be paid to the patentee for the compulsory license, the amount of which is arrived at through an algorithm set out in Regulations.[22] The amount of the royalty is an inverse function of the rank of the importing country on the Human Development Index developed and maintained by the United Nations Development Program. That is, the poorer the country, the less the royalty.[23]

Patentee's rights of action

As set out above, the patentee has three separate causes of action in the JCPA against any generic manufacturer who decides to use the scheme.

The patentee has the right to seek an order in Federal Court that a higher royalty be paid.[24] The court can set the royalty, or order that the royalty be determined in a specified way.

The Court may make such an order "only if it is satisfied that the royalty otherwise required to be paid is not adequate remuneration" taking into account the humanitarian

[21] Section 21.07.
[22] Draft "Use of Patented Products for International Humanitarian Purposes Regulations", Canada Gazette, Part 1, p. 2770, section 8.
[23] For example, the royalty paid for an export to the 177th and last country on the HDI, Sierra Leone, would be, by my calculation, 0.0002 or .02%. The royalty to Namibia (no. 126) would be 1.17%, for Poland (no. 37) 3.18%.
[24] Section 21.08(5).

and non-commercial reasons underlying the issuance of the authorization and the economic value of the use of the invention in the importing country. An order may be "subject to any terms that the Federal Court considers appropriate."

Litigation over the royalty amount introduces uncertainly into the process from the point of view of the generic manufacturer, who will likely have entered into a contractual arrangement to supply a customer before applying for a compulsory license, and yet may have the amount of the royalty increased by the court, seemingly at any time, possibly making the arrangement non-viable. The litigation itself could prove complex and costly and could be brought as a harassing strategy to make it impractical and costly to supply low-cost drugs under the scheme.

No such remedy is required to be given to the patentee under the 30 August Decision.

In addition, the patentee can make an application to the Federal Court to terminate the license, in various circumstances, some of them outside the control of the generic manufacturer.

For example, the license can be terminated if an importing country "has permitted the product to be used for commercial purposes or has failed to adopt the measures [against diversion] referred to in Article 4 of the [30 August] Decision,"[25] or if the product is "re-exported,"[26] or if any of the information provided to the Commissioner "is inaccurate"[27]. But some of that information, such as information about the intent of the importing government, is outside the generic manufacturer's knowledge or control.

The 30 August Decision contains no such requirement that the generic manufacturer police diversion in foreign markets, or be held responsible for whether the importaing

[25] Section 21.14(i).
[26] Section 21.14(f).
[27] Section 21.14.

country fulfills its TRIPS obligations. In the 30 August Decision, it is up to the *importing country* to take "reasonable measures within their means" to prevent diversion.[28] Canadian generic manufacturers are certainly not equipped to police diversion all over the world.

It is doubtful that such a right of action is necessary. If infringing material is re-imported into a country where it should not be, the patentee can and no doubt will enforce its rights using the enforcement measures required by TRIPS to be in place in that country. In Canada, the generic manufacturer has an obvious incentive to abide by the terms of its compulsory license because if it does not do so, it could then be liable for patent infringement.

It is not, I would argue, the intent of the 30 August Decision that the generic manufacturer be made responsible for diversion in overseas markets for the simple reason that this is an impractical way to address the problem, and discourages generic manufacturers from participating.

The uncertainly added by the possibility of such litigation introduces more uncertainties and risks and is a further disincentive to participation in the scheme by generic manufacturers.

"Commercial in nature"

The third subsection conferring power on the patentee to commence litigation against the generic manufacturer was added at third reading. The brand can commence action if the agreement is "commercial in nature."

Under section 21.17, if the price at which the exported product is sold is more than 25% of the "average price in Canada" of the equivalent product, the patentee may seek an

[28] 30 August Decision, paragraph 4

order in Federal Court that the agreement under which the low-cost drugs are sold "is commercial in nature," a term that is not defined.

Factors to be considered in determining whether an agreement is "commercial in nature" include the need of the generic manufacturer to make a "reasonable return," "ordinary levels of profitability in Canada of commercial agreements involving pharmaceutical products," and "international prices."

The generic can avoid an order that the agreement is "commercial in nature" by submitting to "a Court-supervised audit and that audit established 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 percent of that direct supply cost."[29] "Average price in Canada" and "direct supply cost" are defined somewhat ambiguously.

It appears such litigation could involve wide-ranging and complex cross-examination and production on pricing issues both in Canada and around the world. The generic manufacturer, if faced with such litigation, could have an uncertain liability to pay an unknown amount at the conclusion of any such litigation, and a possible order that its products be delivered up to the patentee, notwithstanding that the generic had a compulsory license.[30]

If the Court finds the agreement to be "commercial in nature," whatever that may mean, the license can be terminated, and the court can make such order as it thinks appropriate, including an order that the generic pay, in addition to the royalty "an amount that the Federal Court considers just to compensate the patentee for the commercial use of the patent"[31] or "requiring the holder the 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."[32]

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[29] Section 21.17(5).
[30] Section 21.17(4)(a).
[31] Section 21.17(3).
[32] Section 21.14(4)(a).

In short, after taking all proper steps to obtain a compulsory license, the generic can still be sued for patent infringement. One wonders what the purpose of the scheme is.

The alleged problem the intrusive "commercial in nature" provisions are apparently intended to address is, I submit, imaginary. There is no need for Canadian generic manufacturers to be prevented by the courts from making too much money from exporting drugs to poor countries. Competition among generic manufacturers around the world will ensure prices on such international contracts are low, and participation may well be more in the nature of a charitable gift.

Very few generic manufacturers will seek a compulsory license, even in support of a worthy cause, if by doing so they open themselves to various kinds of hitherto unknown, costly and intrusive litigation turning on ill-defined statutory language.

Two year licence, can be renewed only once

A particularly perplexing feature of the JCPA is that the compulsory license can be for only two years, although it can be renewed for only a further two year period.[33] The JCPA states: "The application may be renewed only once."[34]

It is unclear whether a generic manufacturer can get another compulsory license in respect of the same drug product. Can it make a new application to the Commissioner if it obtains a new contract to supply the same drug to the same party? What about a different party, or in a different country?

Or is the intent that there can be only one renewal per manufacturer in respect of any given drug product? It is difficult to say, because not only is the wording unclear, but

[33] Section 21.09, 21.12(3).
[34] Section 21.12(2).

there seems to be no obvious rationale for such a time limit. People in poor countries may need low-cost drugs just as much and they may be just as poor after four years.

Perhaps the intent of the time limit is that generic manufacturer can sell its product only for four years. If so, the generic manufacturer has only four years to attempt to recoup its investment in formulation development and regulatory approval, which may have taken years to obtain (assuming the patent is still unexpired).

The only purpose of this limitation seems to be to discourage generic manufacturers from participating in the scheme by making it uneconomic for them to do so. The time limit is unnecessary; there is nothing that limits the duration of a compulsory license in TRIPS, nor in the 30 August Decision.

Conclusion

It may be that the government of Canada never had any real intent that JCPA would be used, despite its worthwhile goals, and that the sole purpose of the legislation was simply to get good press for Mr. Chrétien when he retired.

Alternatively, and perhaps more likely, it may be that Mr. Chrétien's stated desire to help the developing world was and is sincere, but that the legislative process somehow went astray once lower-level officials began, perhaps on their own initiative, to accommodate as many patentee lobbying demands into the legislation as possible.

Either way, the result is the same: the JCPA is unworkable in practice for generic manufacturers, the very parties expected to produce the low-cost drugs that are the supposed objective of the scheme.

Appendix "A"

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

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

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

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)

Notes:

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

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. back to text

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. back to text

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. back to text

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

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

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. back to text

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. back to text

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

(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 (3) and that some other Members have stated that, if they use the system, it would be in no more than situations of national emergency or other circumstances of extreme urgency;

(c) "exporting Member" means a Member using the system set out in this Decision to produce pharmaceutical products for, and export them to, an eligible importing Member.

2. The obligations of an exporting Member under Article 31(f) of the TRIPS Agreement shall be waived with respect to the grant by it of a compulsory licence to the extent necessary for the purposes of production of a pharmaceutical product(s) and its export to an eligible importing Member(s) in accordance with the terms set out below in this paragraph:

(a) the eligible importing Member(s) (4) has made a 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 (WT/MIN(01)/DEC/1).

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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.