COMPULSORY LICENSE AND REMUNERATION, INCLUDING SOUTH AFRICAN LAW AND POLICY OPTIONS

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PARIS CONVENTION

Article 5.A

(2) Each country of the Union shall have the right to take legislative measures providing for the grant of compulsory licenses to prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent, for example, failure to work.

…

(4) A compulsory license may not be applied for on the ground of failure to work or insufficient working before the expiration of a period of four years from the date of filing of the patent application or three years from the date of the grant of the patent, whichever period expires last….

TRIPS AGREEMENT 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;

TRIPS AGREEMENT ARTICLE 31

(c) the scope and duration of such use shall be limited to the purpose for which it was authorized,…;

(d) such use shall be non-exclusive;

(e) …

(f) any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use;

(g) ,,,;

(h) the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization;

TRIPS AGREEMENT ARTICLE 31

(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…;

(l) where such use is authorized to permit the exploitation of a patent : …

TRIPS AGREEMENT ARTICLE 44(2)

Article 44

Injunctions

2. Notwithstanding the other provisions of this Part and provided that the provisions of Part II specifically addressing use by governments, or by third parties authorized by a government, without the authorization of the right holder are complied with, Members may limit the remedies available against such use to payment of remuneration in accordance with subparagraph (h) of Article 31. In other cases, the remedies under this Part shall apply or, where these remedies are inconsistent with a Member's law, declaratory judgments and adequate compensation shall be available.

DOHA DECLARATION

5. Accordingly and in the light of paragraph 4 above, while maintaining our commitments in the TRIPS Agreement, we recognize that these flexibilities include:

…

(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.

WORLD BANK TECHNICAL GUIDE

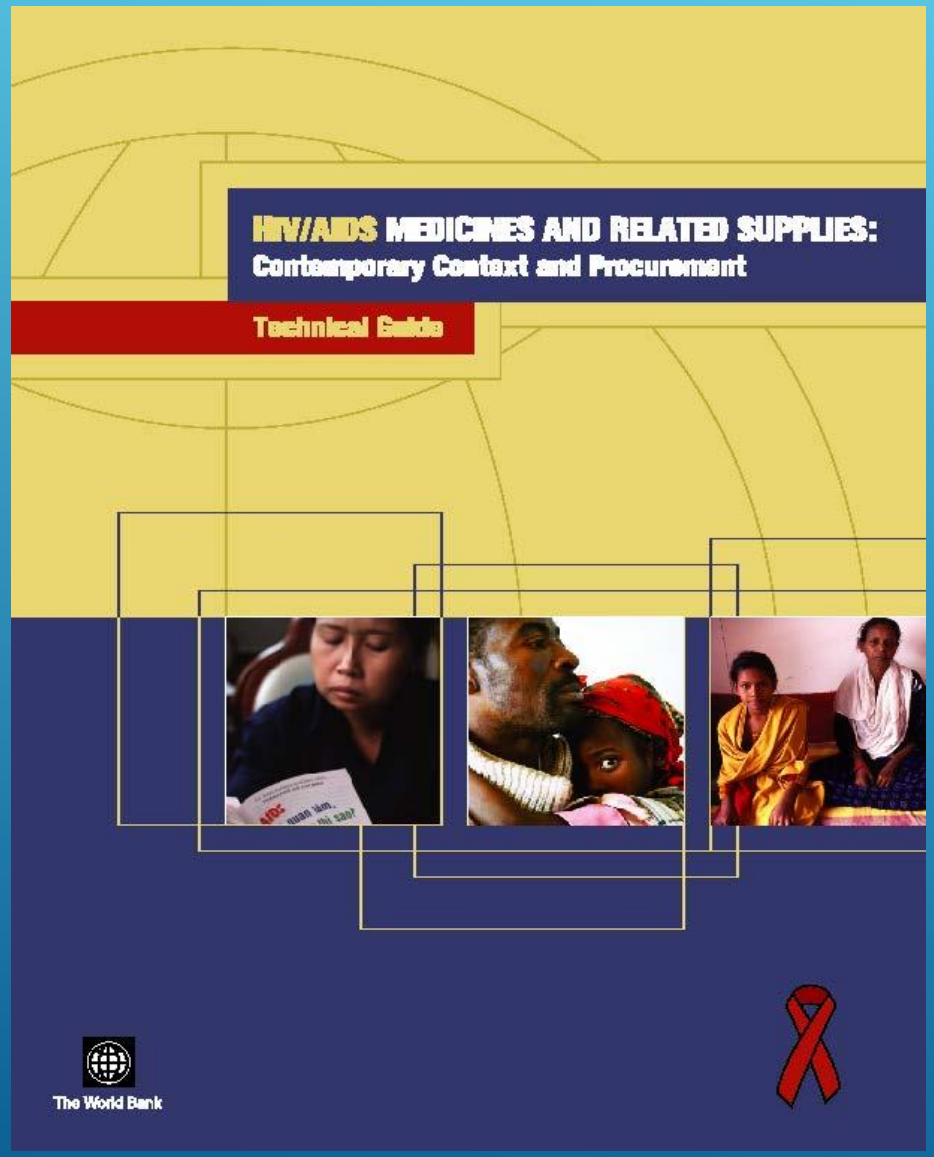


Figure 2.2

INTELLECTUAL PROPERTY RIGHTS CHECKLIST: DEVELOPING COUNTRY

Is there a patent law that allows for patenting of pharmaceutical products?

NO → Then there is no in-country patent obstacle to purchase generic medicines, whether imported or acquired locally → **BUT...** By January 1, 2005 all developing countries are obligated to allow the patenting of pharmaceutical products. Some ARVs that were not under patent before that date will come under patent due to the TRIPS 'mailbox' rule.

YES ↓

Are the specific ARVs under patent nationally?

NO → Then there is no in-country patent obstacle to purchase of generic medicines, whether imported or acquired locally → **BUT...** By January 1, 2005 all developing countries are obligated to allow the patenting of pharmaceutical products. Some ARVs that were not under patent prior to that date will come under patent due to the TRIPS "mailbox" rule.

YES ↓

The procurement authority should have several options under national law. If these options are not now part of national law, the procurement authority should encourage the government to adopt TRIPS-consistent rules that will assist it in purchasing medicines at the most favorable prices.

COMPULSORY LICENSING AND GOVERNMENT USE

The procurement authority may invoke national legislation that permits government use of third party patents in cases of national emergency or circumstances of extreme urgency (the HIV/AIDS pandemic qualifies for such treatment), or for public noncommercial use. The government use license can be used by the procurement authority (or a third party acting on its behalf) to import generic ARVs, or it can be used to authorize local manufacturing.

The government use license should authorize registration of the generic ARV, if it is not already registered under a regulatory review exception. The government is not required to negotiate for a voluntary license from the patent holder, but will be required to pay "adequate remuneration in the circumstances of [the] case, taking into account the economic value of the authorization." The government will determine the amount of the remuneration to be paid to the patent holder, and may take into account its own public health budget and the importance of addressing its people's health needs.

PARALLEL IMPORTING

The procurement authority may "parallel import" the medicine. This means that it will buy the patented version of the medicine at the lowest price available on the world market, regardless of where the medicine is placed on the market. National law should, however, authorize this under a rule of "international exhaustion" of patent rights. Otherwise, the patent holder within the country may be able to block the importation.

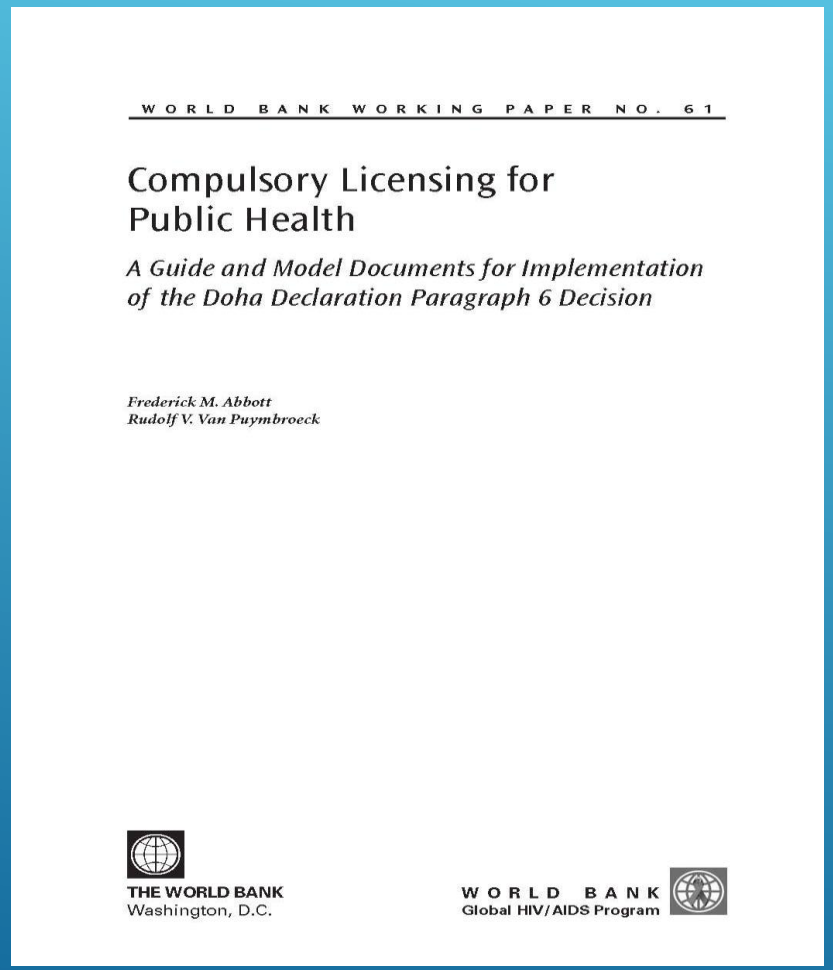
A procurement authority acting on behalf of the government may acquire ARVs from a private party operating under compulsory license. But if the procurement authority is initiating a process to acquire medicines without consent of the patent holder, it would ordinarily act under a "government use" authorization.

Seek price reduction from patent holder or permission to buy generic (in this case, with an agreement from the patent holder not to enforce its patent for such purchase).

The procurement authority is not obligated to pursue these options with the patent holder.

A generic pharmaceutical producer may seek a compulsory license from the government to make or import ARVs. If the private party is addressing HIV/AIDS, it may also be able to avoid prior negotiations with the patent holder because it is dealing with a national emergency or other circumstance of extreme urgency. If the ARVs are to be imported and if the exporter produces under a compulsory license but its production is not predominantly for the supply of its domestic market, then the system established under the WTO's August 30, 2003 "paragraph 6" decision must be applied.

WORLD BANK GUIDE TO PARA. 6



WORLD BANK WORKING PAPER NO. 61

Compulsory Licensing for Public Health

A Guide and Model Documents for Implementation of the Doha Declaration Paragraph 6 Decision

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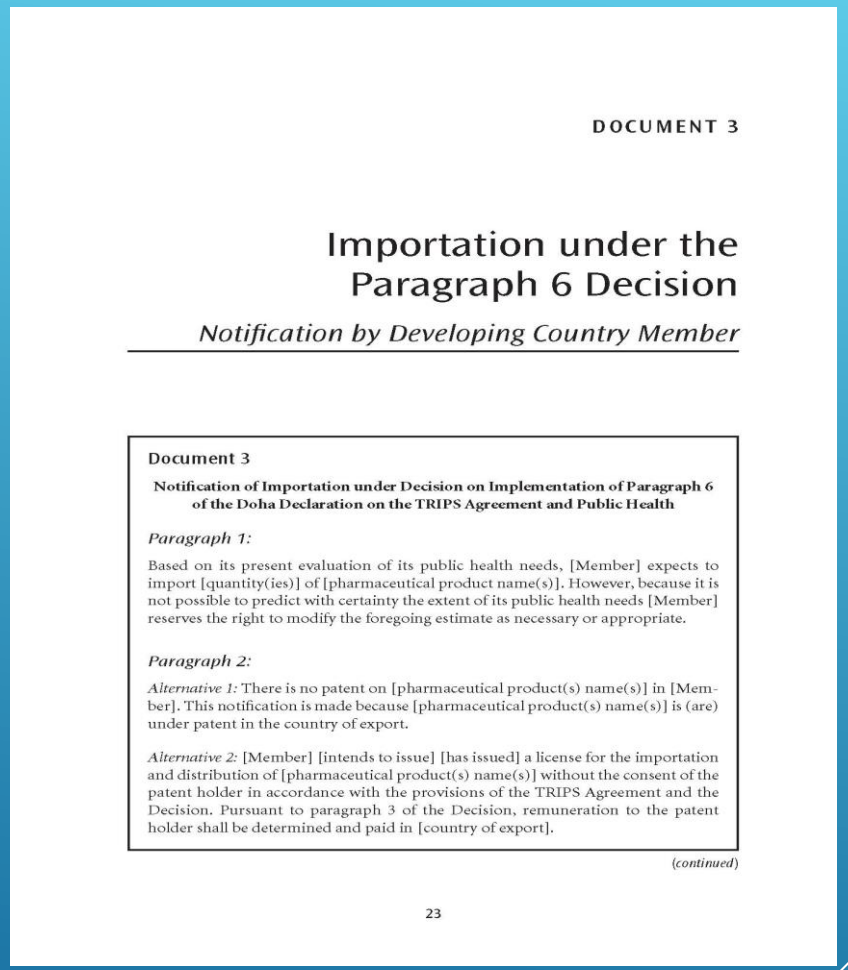

DOCUMENT 3

Importation under the Paragraph 6 Decision

Notification by Developing Country Member

Document 3

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].

(*continued*)

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CARICOM STUDY (WORLD BANK)

4.6.2 Model Non-Voluntary Licensing Provision

1. At the request of an interested person (including the Government), any Minister (or authority designated by the Minister) with responsibility for the subject matter field of a patented invention, or the [Commissioner of Patents], may grant a license to that interested person ("beneficiary"), including without limitation a government entity or a person acting on behalf of such entity, to make use of a patent without the consent of the patent holder (a "non-voluntary license"). A non-voluntary license shall be granted by the Minister (or designee) or [Commissioner] upon determining that:

(a) The public interest would be served by granting the license; or
(b) A national emergency or circumstances of extreme urgency justify the granting of the license; or

CARICOM STUDY (WORLD BANK)

(c) The beneficiary will exploit the license for non-commercial public benefit; or
(d) The license should be granted for the purpose of remedying an anticompetitive practice(s); or
(e) A patented invention that represents a significant technical improvement over another patented invention cannot be adequately exploited without infringement of that other patent.

…

REMUNERATION

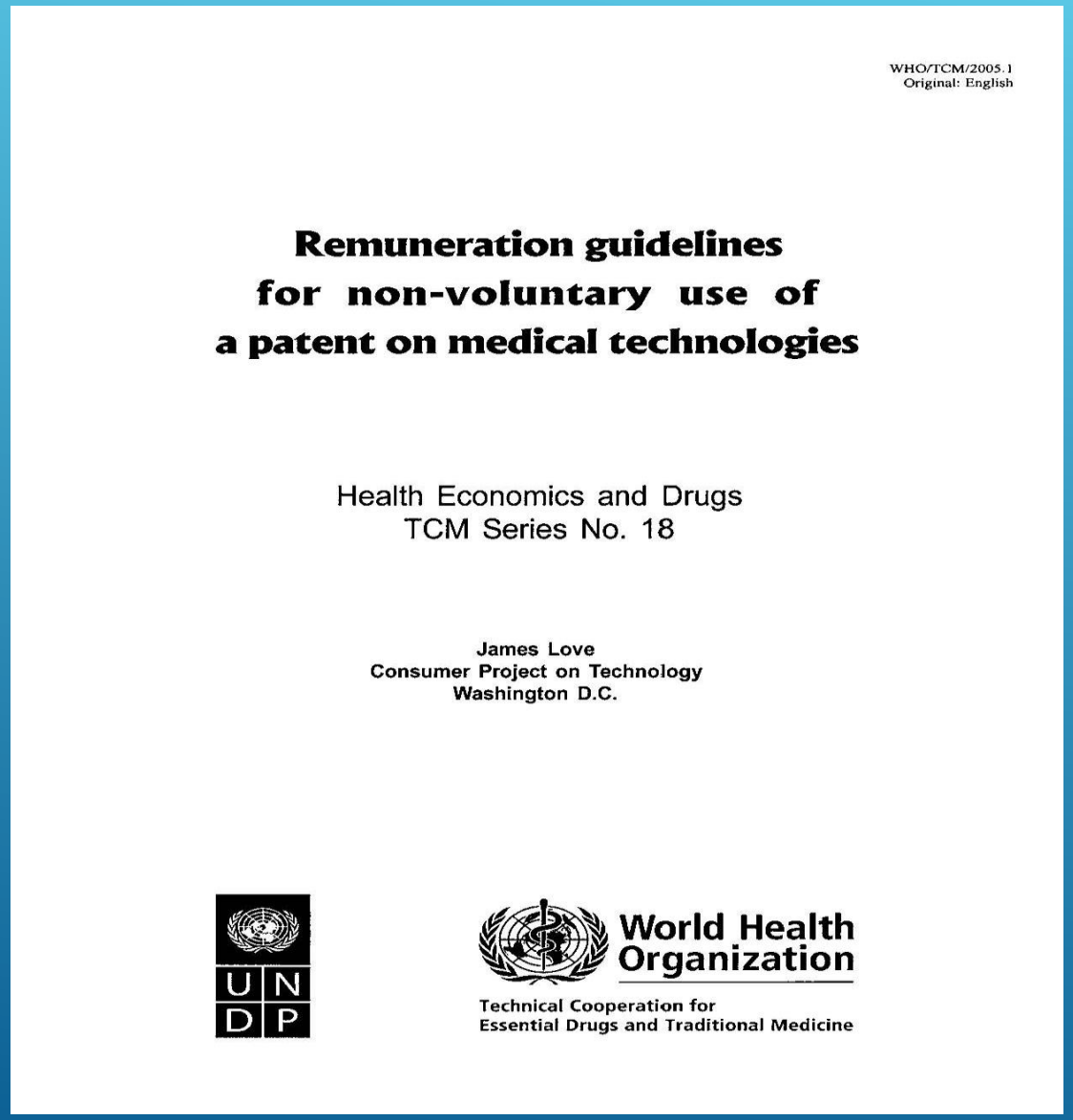
Canada Access to Medicines Regime

Regulations

8. (1) In this section, "Index" means the Human Development Index developed and maintained by the United Nations Development Programme.

(2) For the purpose of subsection 21.08(1) of the Act, the events on the occurrence of which a royalty is required to be paid, and the manner of determining the royalty, are as follows:

REMUNERATION – UNDP/WHO



WHO/TCM/2005.1
Original: English

Remuneration guidelines for non-voluntary use of a patent on medical technologies

Health Economics and Drugs
TCM Series No. 18

James Love
Consumer Project on Technology
Washington D.C.

UNDP

World Health Organization

Technical Cooperation for
Essential Drugs and Traditional Medicine

Referenced by Indian Patent Controller in Bayer-Nexavar case

REMUNERATION

- R&D cost-based allocation model
  - Requires data on R&D costs
  - Scaling based on GDP or other factors
- Alternative models representative of technology industry licensing royalties
- Remuneration not required in competition remedy cases

STREAMLINED AND EFFICIENT

- Procedural aspects fundamental to effective use of compulsory licensing
- Mechanism can be built with presumptions and timing to facilitate grants
- Challenges can be built-in as liability measures (e.g., royalties), just as traditional patent infringement can be addressed by royalties
- Establishing criterion, such as listing of medicine on national essential medicines list, can be object of effectively automatic compulsory license, with eligibility and merits having been established by the legislature,, and allowance made for grant of voluntary license under established conditions

STREAMLINED AND EFFICIENT

- Granting authority need not be limited to patent authority
- Health department authority may be useful, as well as other agencies with specialized interests
- United States government has extremely broad rights to use patents, with remuneration after the fact the sole remedy (28 USC section 1498)