COMPULSORY LICENSING AND GOVERNMENT USE – A COMPARATIVE PERSPECTIVE

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DRAFT INTELLECTUAL PROPERTY POLICY – PHASE I 2017
SOUTH AFRICA
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FROM VIENNA TO PARIS TO THE HAGUE

- Proposals for licensing without consent of patent owner debated in earliest meetings convened to consider international rules in Vienna in 1873
  - "The most notable decision of the conference was paragraph (f) of this resolution which recommended compulsory licensing of patents 'in cases in which the public interest should require it.'" (E. Penrose, 1951)
  - Paris Convention for the Protection of Industrial Property of 1883 did not contain express rules when initially adopted – non-voluntary licensing rules added mainly by Hague Conference in 1925
  - Article 5A introduced broad authority to address abuse and to cancel for non-working

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.

UN HLP RECOMMENDATION

"Governments should adopt and implement legislation that facilitates the issuance of compulsory licenses. Such legislation must be designed to effectuate quick, fair, predictable and implementable compulsory licenses for legitimate public health needs, and particularly with regards to essential medicines. The use of compulsory licensing must be based on the provisions found in the Doha Declaration and the grounds for the issuance of compulsory licenses left to the discretion of governments."

WORLD BANK TECHNICAL GUIDE

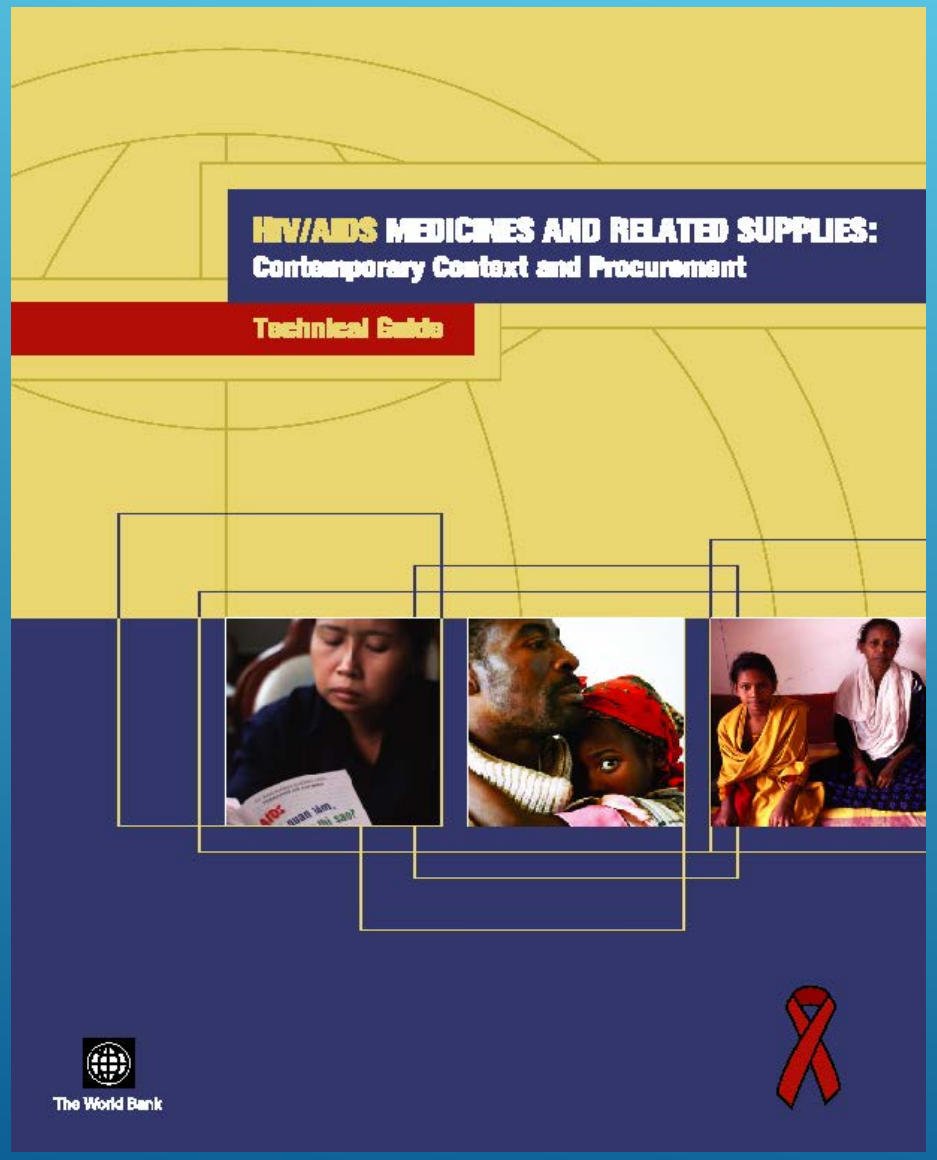


Figure 2.2

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.

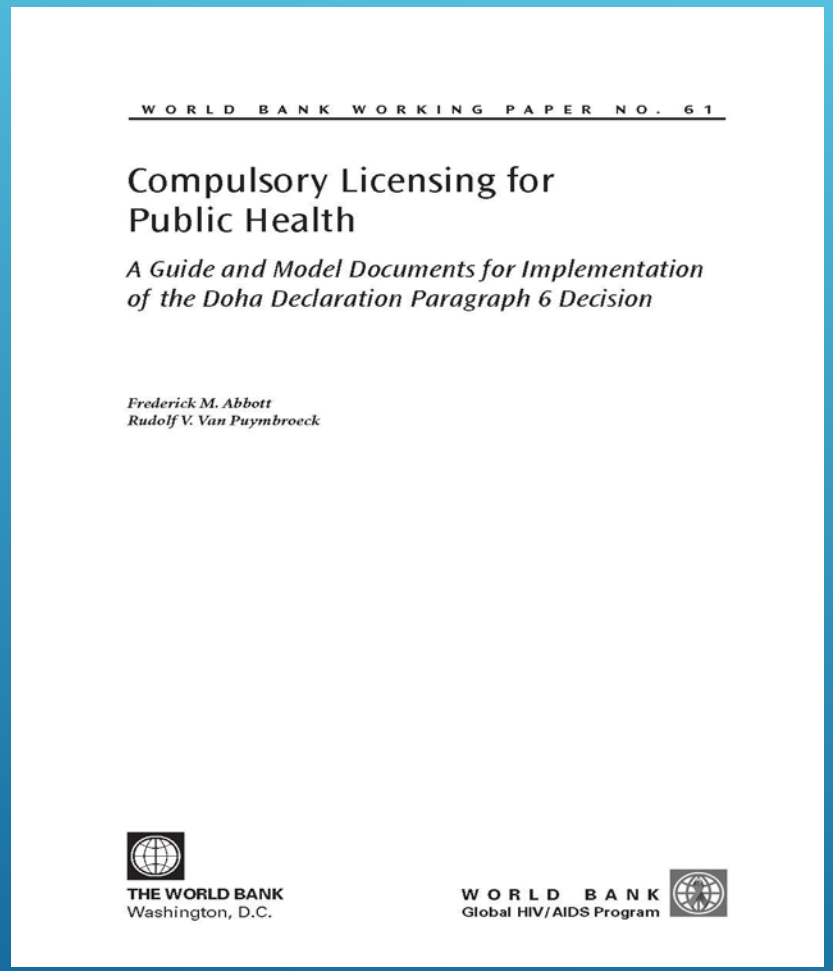
Seek price reduction from patent holder or permission to buy generic (in this case, with an agreement from the patent holder not to enforce its patent for such purchase).

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

A 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.

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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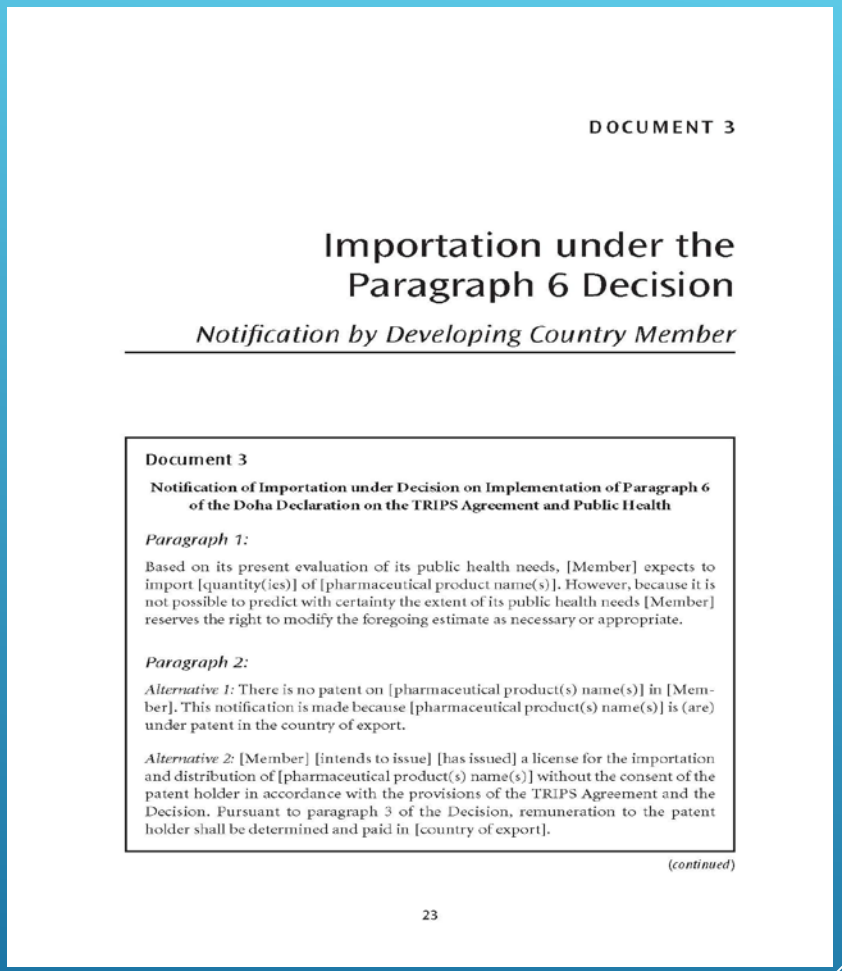
Global HIV/AIDS Program



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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TRIPS ARTICLE 31BIS AND REGIONAL COOPERATION

"3. With a view to harnessing economies of scale for the purposes of enhancing purchasing power for, and facilitating the local production of, pharmaceutical products: 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) shall not apply 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. …"

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

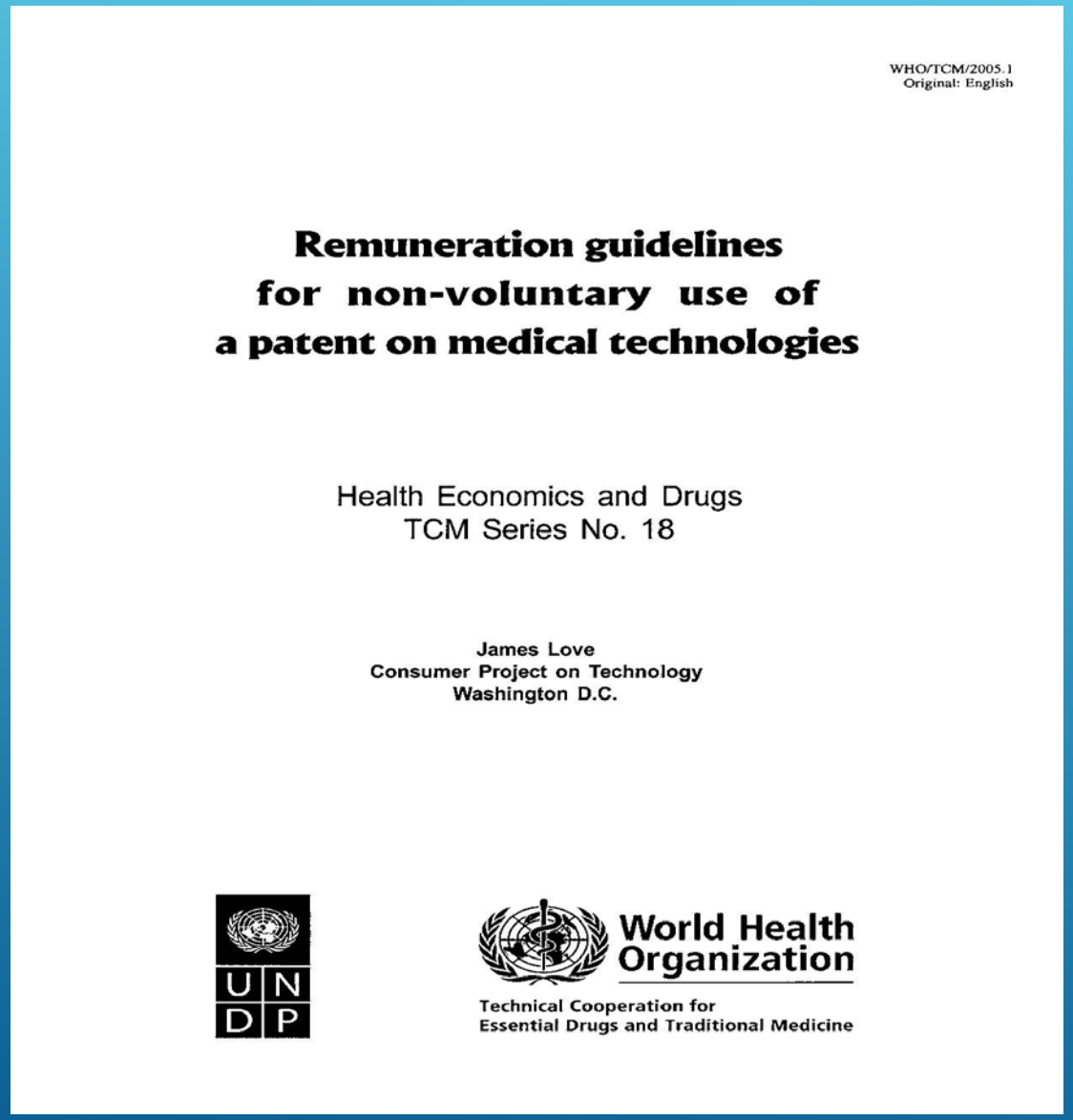
Canada Access to Medicines Regime

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

WIPO SECRETARIAT REPORT ON COMPULSORY LICENSING: SCP/21/4 REV., NOV. 3, 2014

COMPULSORY LICENSING

5. The following Member States (or territories) indicated that their applicable laws provided for exceptions and/or limitations related to compulsory licenses: Albania, Algeria, Argentina, Armenia, Australia, Austria, Azerbaijan, Bangladesh, Belarus, Bhutan, Bolivia (Plurinational State of), Bosnia and Herzegovina, Brazil, Bulgaria, Burkina Faso, Canada, Chile, China and Hong Kong (China), Congo, Costa Rica, Croatia, Cyprus, Czech Republic, Democratic People's Republic of Korea, Denmark, Djibouti, Dominican Republic, El Salvador, Finland, France, Gambia, Germany, Greece, Honduras, Hungary, India, Indonesia, Israel, Italy, Japan, Jordan, Kenya, Kyrgyzstan, Latvia, Lithuania, Madagascar, Malaysia, Mauritius, Mexico, Monaco, Morocco, Netherlands, New Zealand, Norway, Oman, Pakistan, Peru, Philippines, Poland, Portugal, Qatar, Republic of Korea, Republic of Moldova, Romania, Russian Federation, Sao Tome and Principe, Saudi Arabia, Serbia, Slovakia, South Africa, Spain, Sri Lanka, Sudan, Sweden, Switzerland, Tajikistan, Thailand, Turkey, Uganda, Ukraine, the United Kingdom, the United Republic of Tanzania, the United States of America, Viet Nam, Zambia and Zimbabwe (87 in total).

WIPO SECRETARIAT REPORT ON COMPULSORY LICENSING: SCP/21/4 REV., NOV. 3, 2014

Promoting the public interest at large

9. Many other Member States in describing the public policy objectives of the compulsory licensing provisions, as provided in their applicable laws, focused on the interest of the State or the public at large, which are described as, for example, “public interest and interest of society”, “public interest considerations”, “urgent needs of the society”, “development of the economy and the well-being of the society”, “vital interest to the economy of the country, public health or national defense, or where non-working or insufficient working of such patents seriously compromises the country’s needs” and “situations of public interest and emergency motivated by considerations of public health, nutrition and national security”.

SOUTH AFRICA PATENT ACT

56. Compulsory licence in case of abuse of patent rights.

(1) Any interested person who can show that the rights in a patent are being abused may apply to the commissioner in the prescribed manner for a compulsory licence under the patent.

[Sub-s. (1) substituted by s. 45 (a) of Act No. 38 of 1997.]

(1A) . . . . . .

[Sub-s. (1A) inserted by s. 2 (a) of Act No. 76 of 1988 and deleted by s. 45 (b) of Act

No. 38 of 1997.]

(2) The rights in a patent shall be deemed to be abused if—

(a) the patented invention is not being worked in the Republic on a commercial scale or to an adequate extent, after the expiry of a period of four years subsequent to the date of the application for the patent or three years subsequent to the date on which that patent was sealed, whichever period last expires, and there is in the opinion of the commissioner no satisfactory reason for such non-working;

SOUTH AFRICA PATENT ACT

(b) . . . . . .

[Para. (b) deleted by s. 45 (b) of Act No. 38 of 1997.]

(c) the demand for the patented article in the Republic is not being met to an adequate extent and on reasonable terms;

(d) by reason of the refusal of the patentee to grant a licence or licences upon reasonable terms, the trade or industry or agriculture of the Republic or the trade of any person or class of persons trading in the Republic, or the establishment of any new trade or industry in the Republic, is being prejudiced, and it is in the public interest that a licence or licences should be granted; or

(e) the demand in the Republic for the patented article is being met by importation and the price charged by the patentee, his licensee or agent for the patented article is excessive in relation to the price charged therefor in countries where the patented article is manufactured by or under licence from the patentee or his predecessor or successor in title.

SOUTH AFRICA PATENT ACT

4. State bound by patent.

A patent shall in all respects have the like effect against the State as it has against a person: Provided that a Minister of State may use an invention for public purposes on such conditions as may be agreed upon with the patentee, or in default of agreement on such conditions as are determined by the commissioner on application by or on behalf of such Minister and after hearing the patentee.

WIPO REPORT: SCP/21/4 REV., NOV. 3, 2014

66. The response from South Africa noted the "considerable burden of proof on the applicant for compulsory licensing"

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, without notice and with remuneration after the fact the sole remedy by petition to Federal Court of Claims (28 USC section 1498)

  E.g., John R. Thomas, *Compulsory Licensing of Patented Inventions*, Cong. Res. Serv., R43266, January 14, 2014; Colleen Chien, *Cheap Drugs at What Price to Innovation: Does the Compulsory Licensing of Pharmaceuticals Hurt Innovation?,* 18 Berkeley Tech. L. J. 853 (2003)

U.S. GOVERNMENT USE

- Extensive federal jurisprudence
  - See, e.g., *Zoltek Corp. v. United States*, 672 F.3d 1309 (Fed. Cir. 2012)
  - Government use exception consistently recognized in International Trade Commission remedial orders
  - "During the 1950s and early 1960s, the US Department of Defense exercised its right to procure patented pharmaceutical products at substantially reduced prices from sources other than the patent holder—in most cases, from producers in nations, such as Italy that provided no patent protection for pharmaceutical products." F.M. Scherer & J. Watal, *Post-Trips Options for Access to Patented Medicines in Developing Countries*, CMH Working Paper, Nov. 2001
  - Threat by Secretary of Health Thompson to authorize government use of Cipro patent during Anthrax episode following 9/11/2001 – reinforced demands for Doha Declaration

U.S. ANTITRUST REMEDY

The United States has led the world in issuing compulsory licenses to restore competition when violations of the antitrust laws have been found, or in the negotiated settlement of antitrust cases before full adjudication has occurred. By the end of the1950s, compulsory licenses had been issued in roughly 100 antitrust cases covering an estimated 40–50 thousand patents, including AT&T's basic transistor concept patents, IBM's computer and tabulating card machine patents, General Electric's fluorescent and incandescent lamp patents, Du Pont's nylon patents and Eastman Kodak's colour film processing patents. Additional cases since then have led to the licensing of Xerox's plain paper copying machine patents, the tranquilizer Meprobamate, synthetic steroids, the antibiotic Griseofulvin, Cytokine biopharmaceutical patents owned by Novartis and Chiron, and the 9-AC cancer drug patent rights assembled under the merger of Pharmacia AB with Upjohn. Some of the US antitrust decrees, such as those covering General Electric's incandescent lamp patents and the 8,600 patents in AT&T's portfolio, required licensing at zero royalty rates. Most provided for "reasonable" royalties, whose more precise meaning will be investigated subsequently. F.M. Scherer & J. Watal, *Post-Trips Options for Access to Patented Medicines in Developing Countries*, CMH Working Paper, Nov. 2001

U.S. BAYH-DOLE MARCH-IN RIGHTS

(a) With respect to any subject invention in which a [person] has acquired title under this chapter, the Federal agency under whose funding agreement the subject invention was made shall have the right, in accordance with such procedures as are provided in regulations promulgated hereunder to require the contractor, an assignee or exclusive licensee of a subject invention to grant a nonexclusive, partially exclusive, or exclusive license in any field of use to a responsible applicant or applicants, upon terms that are reasonable under the circumstances, and if the contractor, assignee, or exclusive licensee refuses such request, to grant such a license itself, if the Federal agency determines that such—

(1) action is necessary because the contractor or assignee has not taken, or is not expected to take within a reasonable time, effective steps to achieve practical application of the subject invention in such field of use;

(2) action is necessary to alleviate health or safety needs which are not reasonably satisfied by the contractor, assignee, or their licensees;

(3) action is necessary to meet requirements for public use specified by Federal regulations and such requirements are not reasonably satisfied by the contractor, assignee, or licensees; or

(4) action is necessary because the agreement required by section 204 has not been obtained or waived or because a licensee of the exclusive right to use or sell any subject invention in the United States is in breach of its agreement obtained pursuant to section 204.

EBAY LIABILITY ALTERNATIVE

eBay, Inc. v. MercExchange, 547 U.S. 388 (2006)

- Major change to US patent remedy jurisprudence
- Court sets out four factors that patent owner must demonstrate to warrant injunction
  - irreparable injury
  - remedies at law (e.g. damages) inadequate
  - balance of hardships favors patent owner
  - public interest not disserved
- Post-eBay, district court decisions include eBay analysis

COMPULSORY LICENSES ON MEDICINES

Year(s)	Nation	National Income Group	Disease	Disease Group	Total Products	Outcome
2001 (2007)	Brazil	UMIC	HIV/AIDS	HIV/AIDS	2	CL/discount
2001	Brazil	UMIC	HIV/AIDS	HIV/AIDS	1	Discount
2001	Canada	HIC	Anthrax	CD	1	Discount
2001–2003	South Africa	UMIC	HIV/AIDS	HIV/AIDS	8	VL/discount/none
2001	United States	HIC	Anthrax	CD	1	Discount
2002	Egypt	LIC	Erectile dysfunction	NCD	1	CL
2003–2004	Malaysia	UMIC	HIV/AIDS	HIV/AIDS	3	CL
2003, 2007	Brazil	UMIC	HIV/AIDS	HIV/AIDS	1	Discount
2003	Zimbabwe	LIC	HIV/AIDS	HIV/AIDS	All	CL
2004	Mozambique	LDC	HIV/AIDS	HIV/AIDS	3	CL
2004	Zambia	LDC	HIV/AIDS	HIV/AIDS	3	CL
2005–2006	Argentina	UMIC	Pandemic flu	CD	1	VL
2005–2007	Brazil	UMIC	HIV/AIDS	HIV/AIDS	1	Discount
2005–2009	Brazil	UMIC	HIV/AIDS	HIV/AIDS	1	Discount
2005	Ghana	LIC	HIV/AIDS	HIV/AIDS	All	CL
2005	Indonesia	LIC	HIV/AIDS	HIV/AIDS	2	CL
2005	Taiwan	HIC	Pandemic flu	CD	1	VL
2006–2007	India	LIC	Cancer	NCD	1	None
2006 (2010)	Thailand	UMIC	HIV/AIDS	HIV/AIDS	1	CL
2007	Rwanda	LDC	HIV/AIDS	HIV/AIDS	1	CL
2007 (2010)	Thailand	UMIC	HIV/AIDS, CVD	HIV/AIDS, NCD	2	CL
2007–2008	Thailand	UMIC	Cancer	NCD	1	Discount
2007–2008	Thailand	UMIC	Cancer	NCD	3	CL
2010	Ecuador	UMIC	HIV/AIDS	HIV/AIDS	1	CL

Totals: 24 Episodes, 17 Nations, 40 Unique Drug-Nation Combinations +2 Categorical CLs. Years in parentheses indicate CL renewals.
CVD, cardiovascular disease.
doi:10.1371/journal.pmed.1001154.t001

Source: Reed Beall, Randall Kuhn, Trends in Compulsory Licensing of Pharmaceuticals Since the Doha Declaration: A Database Analysis, January 10, 2012https://doi.org/10.1371/journal.pmed.1001154

COMPULSORY LICENSES ON MEDICINES: THAILAND

Timeline Thai Compulsory License

(Source: Ministry of Public Health and the National Health Security Office 2007)
http://www.hitap.net/backoffice/project/pdf_projects/2009-05-20_Final%20report%20-06-301-2551.pdf

- 1992: Introduction of product patent protection
- 2000: Introduction of universal health coverage
- 2003: commitment to provide ARVs for all
- 2005: Thailand sets up Ad Hoc Working Group on price negotiations of patented drugs
- 2006: GUL on efavirenz to import (0.5%)
- 2007: GULs on LPV/r and clopidogrel to import (0.5%)
- 2008: GULs on letrozole, docetaxel, elortinib, (imatinimb)

COMPULSORY LICENSES ON MEDICINES: INDONESIA

Table 1. Licensed medicines (2).

ACTIVE SUBSTANCE	PATENT HOLDER	PATENT NUMBER	DURATION OF PATENT
Efavirenz	Merck & Co., INC	ID 0005812	Until the end of patent period, August 7th, 2013
Abacavir	Glaxo Group Limited	ID 0011367	Until the end of patent period, May 14th, 2018
Didanosine	Bristol - Myers Squibb Company	ID 0010163	Until the end of patent period, August 6th, 2018
Combination Lopinavir and Ritonavir	Abbott Laboratories	ID 0023461	Until the end of patent period, August 23rd, 2018
Tenofovir	Gilead Sciences, Inc.	ID 0007658	Until the end of patent period, July 23rd, 2018
Combination of Tenofovir and Emtricitabine Combination of Tenofovir, Emtricitabine and Evafirenz	Gilead Sciences, Inc.	ID P0029476	Until the end of patent period, 3rd November 2024

Indonesian President Susilo Bambang Yudhoyono issued a decree on 3rd September 2012 that allows the government to use patents for seven HIV/AIDS and hepatitis B medicines. "We will ensure the availability of good quality, safe and effective generic versions of anti-retroviral and anti-viral drugs," said HM Subuh, Infectious Disease Control Director at the Indonesian Health Ministry, as quoted in The Jakarta Post on 19th October. G. Velasquez, Special Adviser for Health and Development at the South Centre, Geneva, December 2012

COMPULSORY LICENSE: INDIA

- India Controller of Patents grants compulsory license on Bayer drug, Nexavar, in favor of NATCO, March 9, 2012
  - Three grounds applied
    - Lack of accessibility
    - Lack of reasonable affordability
    - Failure of local working
  - Bayer had supplied very limited quantities to the Indian market
    - Bayer argued that Cipla already adequately supplying market, so that compulsory license unnecessary
    - Bayer introduced limited evidence of program designed to provide accessible-affordable product

COMPULSORY LICENSE: INDIA

- Prices far in excess of those affordable to the public, including with government assistance
- Had sought to supply requirements only through importation, and had not demonstrated sufficient obstacle to local production
- Bayer alleges Cipla production infringes patent, cannot rely on activities it claims are illegal as defense

- Affirmed by Intellectual Property Appellate Board on March 4, 2013
- Minor variation in ruling on local working
- Supreme Court dismisses appeal, December 12, 2014

BRAZIL TO WTO TRIPS COUNCIL, JUNE 13-14, 2017

- Compulsory license in 2007 on efavirenz, an antiretroviral used by 40 percent of HIV patients in Brazil (at the time).

"In spite of strictly following the requirements contained in the national and international legal framework, the Brazilian Government faced legal disputes in national courts, which were initiated by the owner of the patent. These disputes, however, were not successful.

As a result of such efforts by the Brazilian Government, and taking full advantage of legally permissible limitations and exceptions, it was possible to substantially reduce the price of Efavirenz from US$ 1,59 to US$ 0,45 per tablet at nominal prices. This helped to ensure the adequate provision of medicine to HIV patients who need to take it on a daily basis to keep the disease under control."

MALAYSIA GRANTS GOVERNMENT USE LICENSE ON SOFOSBUVIR

The Malaysian government on 20 September [2017]confirmed that it approved "the use of Rights of Government under Patent Act 1983 (Act 291) by exploiting the patented invention of Sofosbuvir tablet 400mg." According to a press release, "the last time Malaysia instigated the Rights of Government was in 2003 for anti-retroviral drugs (treatment for HIV infection). This sets Malaysia to be the first country to initiate such move in the world."

The decision to initiate the Rights of Government, the release said, "was made after the MOH [Ministry of Health] efforts to be included in the Medicine Patent Pool (MPP) and price negotiations with patent holder were unsuccessful."

C. Saez, IP-Watch, Sept. 15, 2017

SOUTH AFRICA SUBMISSION TO WTO TRIPS COUNCIL

On 20 October 2017, South Africa delivered the following statement on behalf of Brazil, China, India, and South Africa during the WTO TRIPS Council's discussions on compulsory licensing.

“A common theme that emerged from discussions was how governments use compulsory licenses to substantially reduce the price of essential medicines while striking a balance between the interest of right holders and users.

…

… a balanced intellectual property system, through a combination of flexibilities, complementary policies and incentives, guarantee sustainable public health outcomes that harness innovation and promotes access to medicines and health technologies.”