Patents and Morality- Access to Medicines

Professor Michael Blakeney

Michael.blakeney@uwa.edu.au

Outline

- Patent law principles
- Compulsory Licensing
- HIV/AIDS Crisis
- Confidential Information
- WHO initiatives

Patent Law Principles-TRIPS Art.27.1

- …patents shall be available for any inventions, whether products or processes, in all fields of technology, …
- patents shall be available and patent rights enjoyable without discrimination as to … the field of technology ….

TRIPS Art.27.2

2. Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public or morality, including to protect* human, animal or plant life or health or to avoid serious prejudice to the environment...

Paris Convention Art. 5

(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.

TRIPS Art 31

Where the law of a Member allows for use of the subject matter of a patent without the authorization of the right holder, ... 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 noncommercial use. In situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonably practicable.

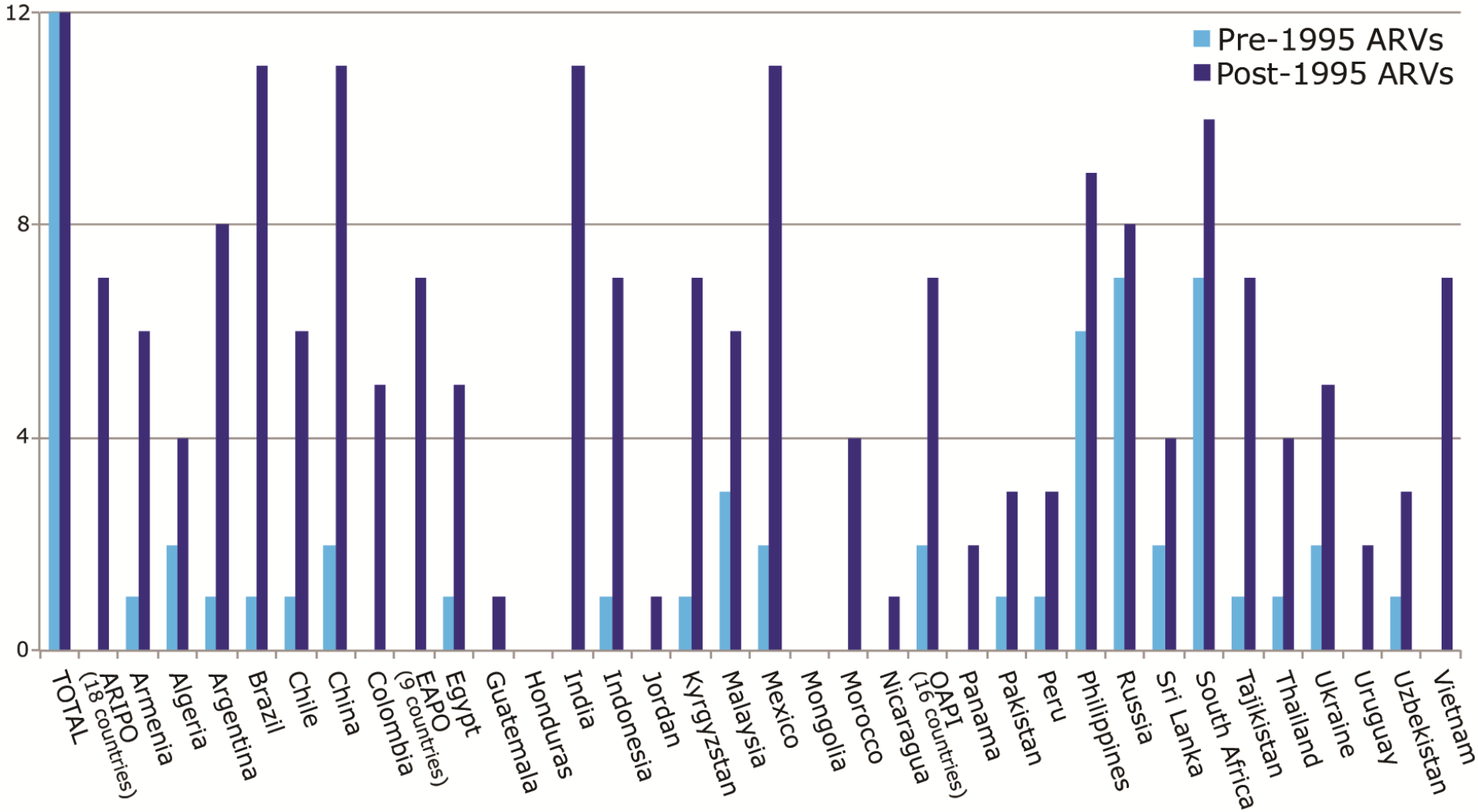
TRIPS Art 31

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

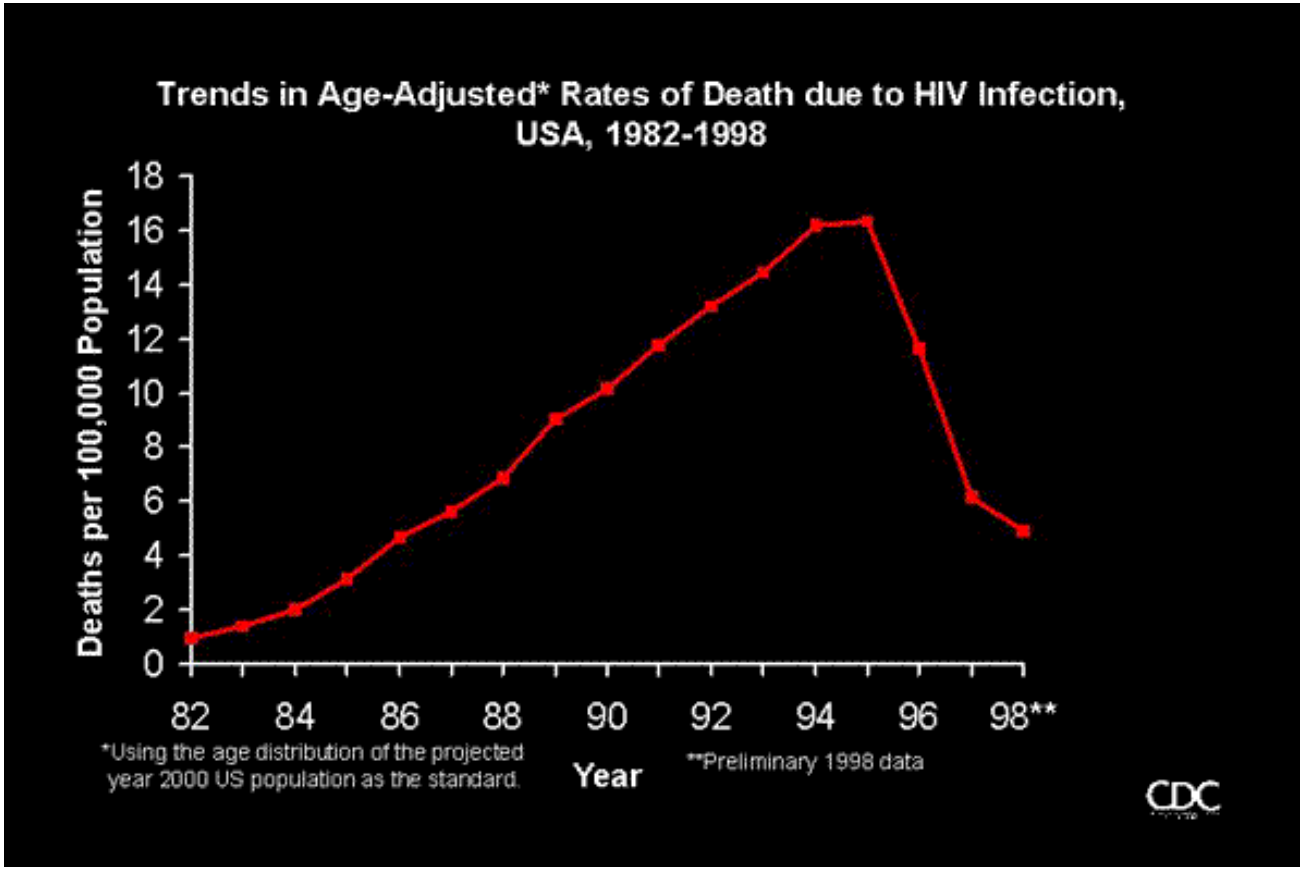
Public Health Crisis

- <5% of est. $44 billion on R&D concerns developing country diseases, while only 13 of the 1,393 new drugs approved between 1975 and 1999 are concerned with tropical diseases. UK Commission on IPR, *Integrating IPRs and Development Policy*, (2002), at 32
- Of the >33 million HIV-positive people in the world, 95 per cent live in developing countries, and most of them cannot afford the necessary drugs (*Statement of UNAIDS at the Third WTO Ministerial Conference*, Seattle, 30 Nov.-3 Dec. 1999).
- majority of HIV vaccines being developed for genetic profiles of subtype B; while most AIDS sufferers in developing countries are types A and C

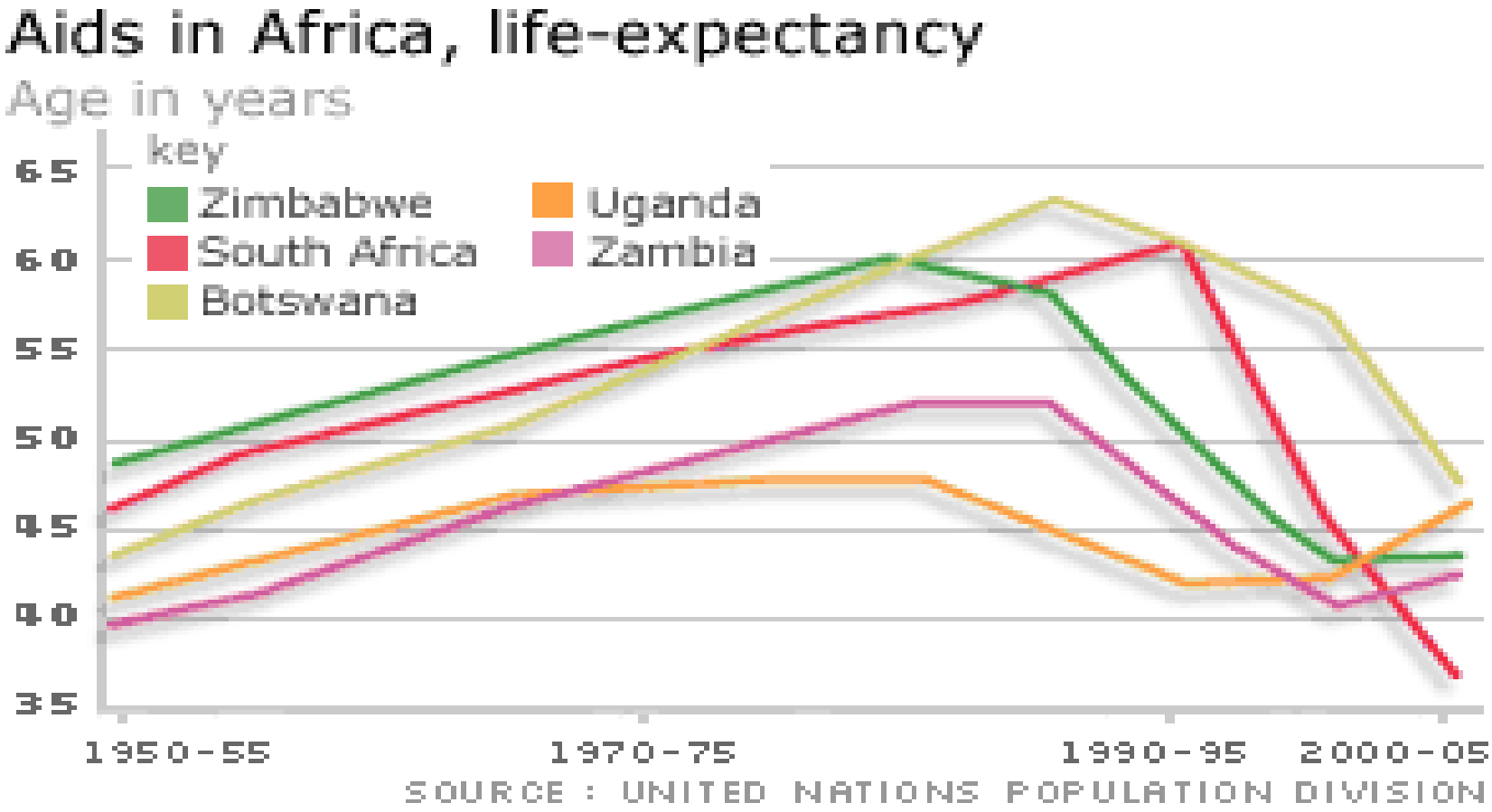
Patents on HIV Medicines



AIDS death rates drop in the U.S. and other rich countries



But life expectancy plummets in Africa.



Costs of Major AIDS Drugs

- Large disparity between price and production costs provides big incentives for generics to enter market

Drug	Form	Price	Production Cost	% Difference
Ciprofloxacin	250 mg tab	$3.40	$0.05	98
ddI	100 mg cap	$1.80	$0.50	72
EFV	200 mg cap	$4.40	$2.40	48
Fluconazole	200 mg cap	$12.20	$0.30	98
3TC	150 mg cap	$4.50	$0.30	93
NVP	200 mg cap	$4.90	$1.50	73
d4T	40 mg cap	$4.90	$0.20	96
AZT	100 mg cap	$1.70	$0.10	94
AZT+3TC	300+150 mg cap	$9.80	$0.70	93

Patents and Public Health

Patents are not a significant barrier to the treatment of HIV/AIDS in Africa, with a variety of other factors such as poverty, tariffs and sales taxes and a lack of sufficient international financial aid to fund anti-retroviral treatment, being of greater significance.

Amir Attaran and Lee Gillespie-White ‘Do Patents for Antiretroviral Drugs Constrain Access to AIDS Treatment in Africa?’, 286 (15) Journal of the American Medical Association 1886 (2001).

Generic Drugs

TRIPS 31(f), generic drugs produced under a compulsory licence ‘shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use’

Only China, India, Brazil, Argentina and South Africa have manufacturing capacity to produce significant quantities of off-patent generic drugs.

IN THE HIGH COURT OF SOUTH AFRICA
(TRANSVAAL PROVINCIAL DIVISION)
Case no: 4183/98
In the matter between:
PHARMACEUTICAL MANUFACTURERS' ASSOCIATION OF SOUTH AFRICA AND OTHERS
Applicants
and
THE PRESIDENT OF THE REPUBLIC OF SOUTH AFRICA AND OTHERS
Respondents
and
TREATMENT ACTION CAMPAIGN (TAC)
Amicus Curiae

Amendments to the South African *Medicines and Related Substances Control Act* No. 101 of 1965

Section 15C

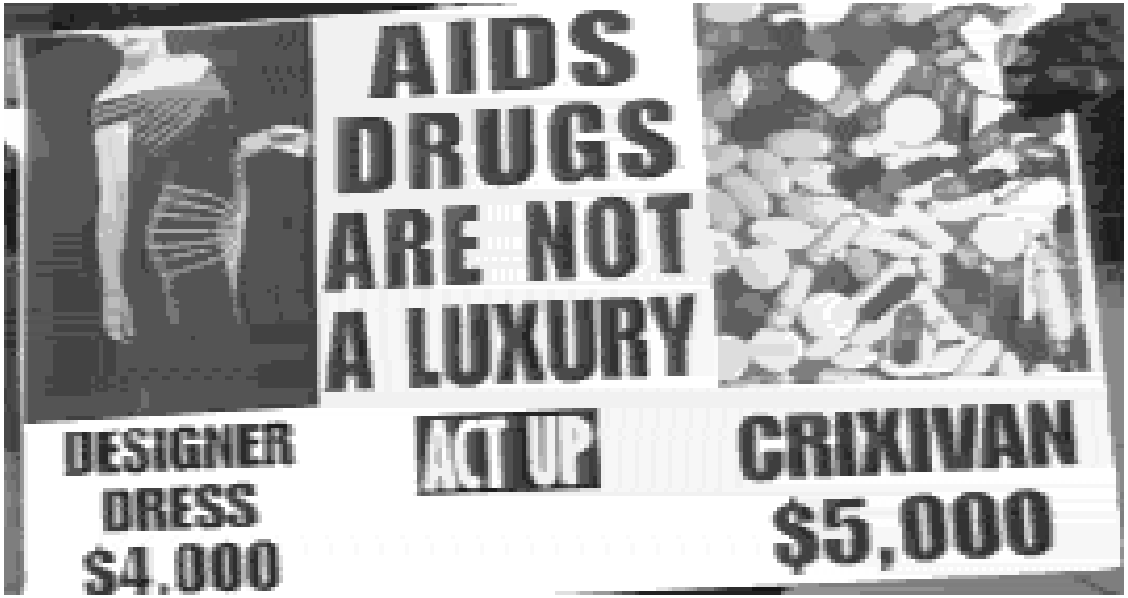
The minister may prescribe conditions for the supply of more affordable medicines in certain circumstances *so as to protect the health of the public*, and in particular may-

(a) notwithstanding anything to the contrary contained in the Patents Act, 1978 (Act No. 57 of 1978), determine that the rights with regard to any medicine under a patent granted in the Republic shall not extend to acts in respect of such medicine which has been put onto the market by the owner of the medicine, or with his or her consent;

Pharmaceutical Manufacturers Association of South Africa: In re Ex Parte President of the Republic of South Africa and Others (CCT31/99) [2000] ZACC 1 [Constitutional Court}

- Para 89 The President's decision to bring the Act into operation cannot be found to be objectively rational on any basis whatsoever.
- What the Constitution requires is that public power vested in the executive and other functionaries be exercised in an objectively rational manner. This the President manifestly, though through no fault of his own, failed to do.

Essential medicines are not luxury goods, reserved for the wealthiest of the world…



…but are too often priced like them, causing preventable suffering and death.

NGO response

- Cooper H., Zimmerman R., McGinley L.: *Patents Pending: AIDS Epidemic Traps Drug Firms In a Vise: Treatments vs. Profits. Wall Street Journal* (Mar 2, 2001)
- “Can the pharmaceuticals industry inflict any more damage upon its ailing public image? Well, how about suing Nelson Mandela?”.

Political response

- WTO Seattle Ministerial Meeting (1999)
- President Clinton referred specifically to the situation in South Africa and the HIV/AIDS crisis, saying that “the United States will henceforward implement its health care and trade policies in a manner that ensures that people in the poorest countries won’t have to go without medicine they so desperately need.”
- W.J Clinton: *Remarks at a World Trade Organization Luncheon in Seattle.* Weekly Comp Pres Doc 1999, Dec 1; 35: 2494, 2497.

- May 2000, President Clinton confirmed the change in United States policy by issuing an Executive Order on Access to HIV/AIDS Pharmaceuticals and Medical Technologies, supporting the use of compulsory licenses to increase access to HIV/AIDS medication in sub-Saharan Africa
- Exec Order No 13,155, 65 Fed Reg 30,521, 2000.

US-Brazil WTO Dispute

- US complaint: Art. 68 Brazil Industrial Property Law (Law 9.279/96), which permitted the granting of a compulsory licence where there is a lack of local manufacturing of the patented product, incompatible with the principle of non-discrimination in Article 27(1) of TRIPS.
- In the face of criticism from the international community, the US withdrew its complaint and notified: Mutually Agreed Solution, *Brazil – Measures Affecting Patent Protection* (WT/DS/199/4, 19 July 2001), following Brazil's commitment to hold talks should Brazil consider it necessary to use Art 68 grant a compulsory licence on patents held by US companies.

Doha Declaration on the TRIPS Agreement and Public Health

WORLD TRADE
ORGANIZATION

WT/MIN(01)/DEC/W/2
14 November 2001
(01-5770)

MINISTERIAL CONFERENCE
Fourth Session
Doha, 9 - 14 November 2001

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.

WTO DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH

5 (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.

WTO DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH

5 (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) …each Member free to establish its own regime for …exhaustion without challenge, subject to the MFN and national treatment provisions of Articles 3 and 4.

WTO DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH

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.

Amendment of the TRIPS Agreement
Decision of 6 December 2005

Noting the Declaration on the TRIPS Agreement and Public Health (WT/MIN(01)/DEC/2) 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;

Decides as follows:

1. The Protocol amending the TRIPS Agreement attached to this Decision is hereby adopted and submitted to the Members for acceptance.
2. The Protocol shall be open for acceptance by Members until 1 December 2007 or such later date as may be decided by the Ministerial Conference.
3. The Protocol shall take effect in accordance with the provisions of paragraph 3 of Article X of the WTO Agreement.

PROTOCOL AMENDING THE TRIPS AGREEMENT

1. The Agreement on Trade-Related Aspects of Intellectual Property Rights (the "TRIPS Agreement") shall, upon the entry into force of the Protocol pursuant to paragraph 4, be amended as set out in the Annex to this Protocol, by inserting Article 31bis after Article 31 and by inserting the Annex to the TRIPS Agreement after Article 73.

ANNEX TO THE PROTOCOL AMENDING THE TRIPS AGREEMENT

Article 31bis

1. The obligations of an exporting Member under Article 31(f) shall not apply 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 in paragraph 2 of the Annex to this Agreement.

ANNEX TO THE TRIPS AGREEMENT

1. For the purposes of Article 31bis and this Annex:

(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 on the TRIPS Agreement and Public Health (WT/MIN(01)/DEC/2). 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 to the Council for TRIPS of its intention to use the system set out in Article 31bis and this Annex (“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.

The terms referred to in paragraph 1 of Article 31bis are that:
(a) the eligible importing Member(s) has made a notification to the Council for TRIPS, that:

(i) specifies the names and expected quantities of the product(s) needed;

(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 Appendix to this Annex; 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 Articles 31 and 31bis of this Agreement and the provisions of this Annex;

Compulsory Licensing of ARVs: The Case of Thailand

- Between October and January 2007, the Thai government issued compulsory licenses for four patented medicines including Abbott's ARV, Kaletra.

HIV/AIDS prevalence in Thailand

- In 2004 500,000 people were reported to be living with HIV-AIDS in Thailand.

- As of 2006, 78,000 people receiving ARV treatment, more than 90% of those who needed it.

- However, estimated that approximately 12,000 HIV positive people in the country have developed drug resistance to the first line treatment.

- Price of second line ARVs was about $2,200 or 73,000 baht per person per year.

Estimated outcomes of accessible second-line therapy

- Thai government estimated it would save 8,000 lives per year, by making distribution of second-line ARV therapy possible to people who could not afford it.

- The World Bank estimated Thailand could reduce the cost of second-line therapy by 90% if it introduced compulsory licenses for all the drugs it needed in second-line therapy, saving itself $3.2 billion over the next 20 years.

Thailand & the right to medicine

- Under Thailand's National Health Security Act 2001, the Thai government is mandated to achieve universal access to essential medicines.

- Since October 2003, the Thai government committed to providing universal access to antiretroviral (ARV) treatment for all AIDS patients.

U.S. and Thai Law on Gov. Use Licenses

- Section 51 of the Thai Patent Act permits any ministry, bureau or department of the Government to issue a license for “public consumption” of generic medicines without prior negotiations with the patent holder, subject only to an obligation to a set a royalty rate which is thereafter reviewable by the patent owner.

Trade Threats

- Thai gov't CL decision stimulated trade threats by Abbott, the US government and pharmaceutical companies.

- Civil society organizations and Abbott investors renounced threats as unethical and morally unacceptable.

Price Cuts - Victory

- In April 2007 Abbott cuts the price of Kaletra to 3,488 baht per month
- Abbott further lowers the cost to $1,000 per patient per year in more than 40 low-and middle-income countries including Thailand.

March 14, Abbott bombshell

- Abbott withdrew heat-stable lopinavir/ritonavir (Kaletra) and six other medicines from the Thai drug registration process.
- April 10, Abbott dropped its price for Kaletra from $2200 to $1000 for 45 low- and lower-middle income countries, but still refuses to introduce Aluvia in Thailand.

April 30, 2007 Thailand on 301 Priority Watch List.

Grounds:

- "Overall deterioration in the protection and enforcement of IPR in Thailand."
- "Weakening respect for patents (decision to issues several compulsory licenses)."
- "Lack of transparency and due process ... represents a serious concern."
- "[Ongoing] concerns such as delay in the granting of patents and weak protection against unfair commercial use for data generated to obtain marketing approval."

Developments in Congress

- Prescription Drug User Fee Amendments Act of 2007 (S. 1082, the Food and Drug Administration Revitalization Act)
- Sec. 516. Sense of the Senate regarding certain patent infringements.
  - (a)(6) “There are concerns that certain countries have engaged in ... abuse of compulsory licensing.”
  - (b)(2) “[The USTR] should develop and submit to Congress a strategic plan to address the problem of countries that infringe upon American pharmaceutical intellectual property rights.”

Subsequent Developments

- May 4 – Brazil issued a compulsory license on Efavirenz
- May 8 – Clinton Foundation announced generic, heat-stable Kaletra at $695/year.
- June 20 – Sen. Res. 241 (pro-Doha Declaration)
- June 28 – USTR announces loss of $1 billion duty-free privileges for Thailand for three product classes under GSP.
- July 20 – US Ambassador to Thailand writes protesting deliberations on issuing additional compulsory licenses
- October 17 –Thai Food and Drug Administration announced registration of generic LPN/r produced by Matrix (India); GPO announced that it was ordering a six-month supply for 8000 patients at a cost of $695/pppy.

South Africa - Pharma Industry Response

Motsoaledi: Big pharma's 'satanic' plot is genocide

http://mg.co.za/print/2014-01-16-motsoaledi-big-pharmas-satanic-plot-is-genocide

- Health minister Aaron Motsoaledi is livid about a pharmaceutical company campaign he says will restrict access to crucial drugs.

- "I am not using strong words; I am using appropriate words. This is genocide," Motsoaledi told the *Mail & Guardian* on Thursday, in response to a plan he described as a conspiracy of "satanic magnitude" – a plan he called on all South Africans to fight "to the last drop of their blood".
- The plan in question is a nine-page document obtained independently this week by both the *M&G* and the department of health, blandly titled *Campaign to Prevent Damage to Innovation from the Proposed Draft National IP Policy in South Africa*.

- The drug companies' umbrella body, the Innovative Pharmaceutical Association of South Africa (Ipasa), selected a Washington, DC-based, lobbying firm Public Affairs Engagement (PAE) to lead the charge against the policy.

The plan includes:

- Setting up a "coalition" with the name "Forward South Africa", which will be directed from Washington while appearing to be locally run;
- Encouraging other African countries, especially Rwanda and Tanzania, to help to convince SA that it could lose its leadership role on the continent should it push ahead with the draft policy;
- Commissioning "independent" research and opinion pieces for broad public dissemination – but vetting all such material before publication to ensure it fits the message.

TRIPS Art 39 Data Exclusivity

3. Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use.

During the exclusivity period: Generic manufacturers will have to submit their own data to prove safety and efficacy

Alternatively, they can only enter the market after expiry of the data exclusivity period

ENCYCLICAL LETTER

CARITAS IN VERITATE

OF THE SUPREME PONTIFF

BENEDICT XVI

TO THE BISHOPS

PRIESTS AND DEACONS

MEN AND WOMEN RELIGIOUS

THE LAY FAITHFUL

AND ALL PEOPLE OF GOOD WILL

ON INTEGRAL HUMAN DEVELOPMENT

IN CHARITY AND TRUTH

October 2009

CARITAS IN VERITATE

- para 22: "Corruption and illegality are unfortunately evident in the conduct of the economic and political class in rich countries, both old and new, as well as in poor ones. Among those who sometimes fail to respect the human rights of workers are large multinational companies as well as local producers. ...On the part of rich countries there is excessive zeal for protecting knowledge through an unduly rigid assertion of the right to intellectual property, especially in the field of health care".