Medicines Law & Policy

The Power of Law. How can NGOs Promote Access to Medicines through Legal Procedures – PAF 22 Nov 2021

The case of the TRIPS Agreement and its flexibility

Ellen ‘t Hoen, LLM, PhD

Interest declaration

- No fee for lecture
- Self-employed: work for not-for-profits, academia, governments, UN (sometimes paid sometimes not)
- Grant from unitaid to work on covid
- Our work is open access and freely available on:

www.medicineslawandpolicy.org

Intellectual property

- Intellectual property (IP) refers to the legal rights which result from intellectual activity in the industrial, scientific, literary and artistic fields. IP has two branches:
  - Industrial property e.g.:
    - Inventions (patents)
    - Trademarks
    - Industrial designs
    - Geographical indications
  - Copyright
    - Related rights (neighbouring rights)

History of TRIPS

- TRIPS negotiations started in the Uruguay Round of the General Agreement on Tariffs and Trade (GATT '86 – '94)
- '86 Drug companies established an elite, high powered lobby group to ensure intellectual property issues would be part of the GATT framework
- TRIPS contentious
  - 49 of the 98 members of the Paris Convention excluded medicines from patentability or had shorter protection periods
  - Andean Community excluded WHO essential medicines from patents (1991-2000)
  - Medicines patent introduction: France '60, Switzerland '77, Italy '78, Sweden '78, Spain '92, India '05
  - Inclusion of TRIPS in the GATT took place under pressure of trade sanctions by the US.

1995 Globalising Intellectual Property Norms

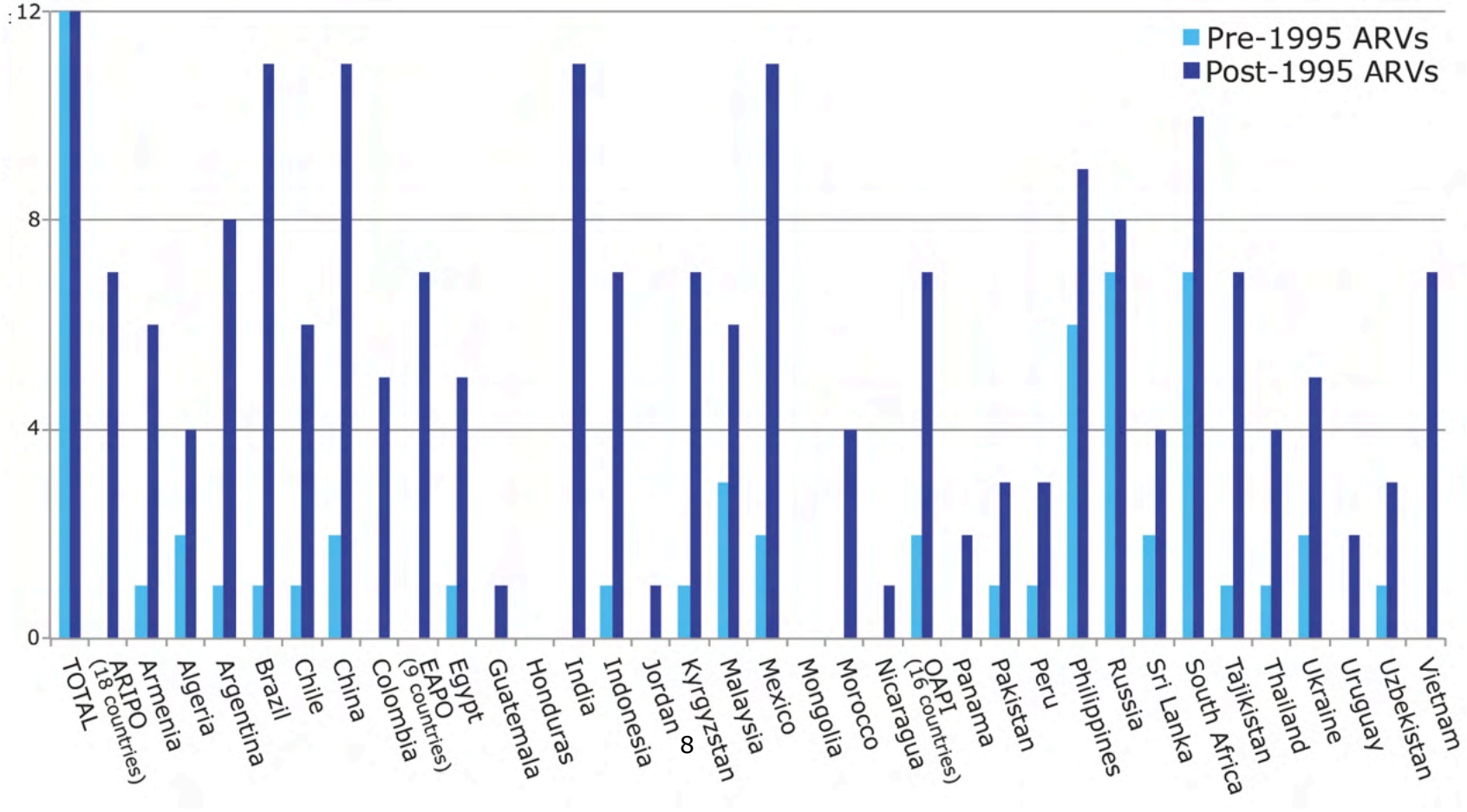
- TRIPS Agreement
- Requires all WTO countries to provide patents (min 20y)
- No exceptions possible for entire fields of technology
- Transition periods for LDCs and DC with production (e.g. India)

No civil society involvement in the negotiations of GATT and thus the TRIPS Agreement

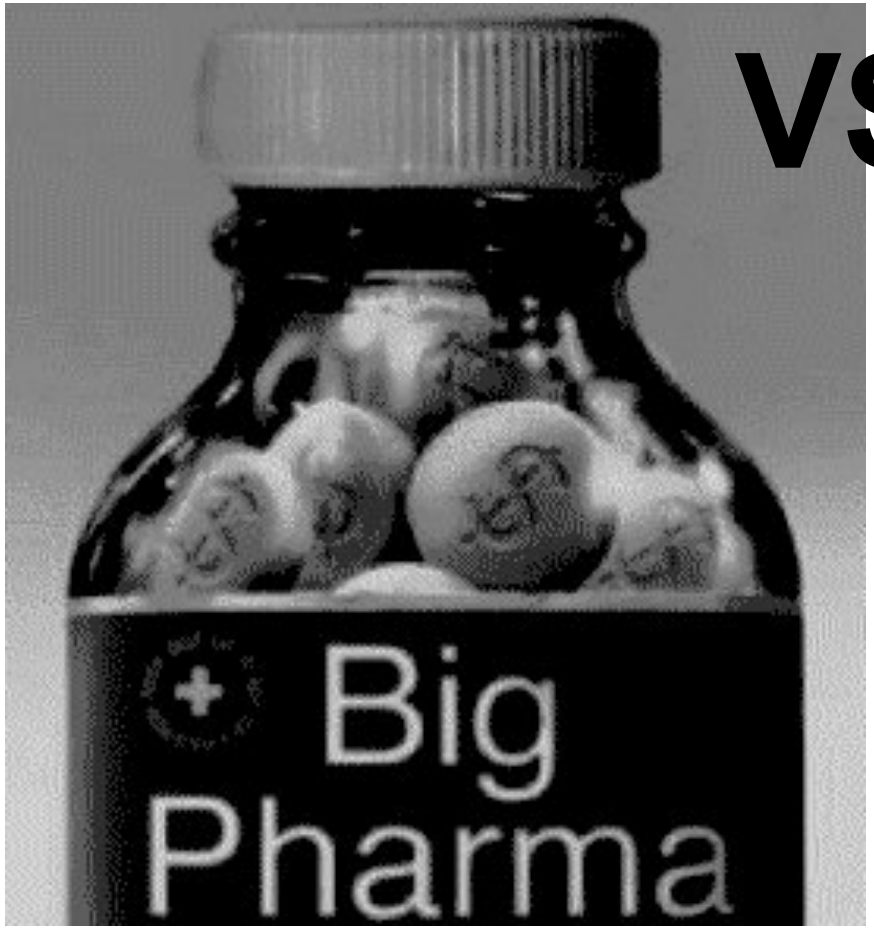
What else happened around that date?

- Over 40 million people with HIV
- AIDS medicines cost US$ 10-15.000 pppy
- Not available in most LMI countries – except those that had local production e.g. Brazil and Thailand.
- 8000 people a day dying while lifesaving medicines were available in the west.
- Mobilisation of civil society.
- Drug companies using legal procedures ->

Pre/post TRIPS patenting HIV medicines



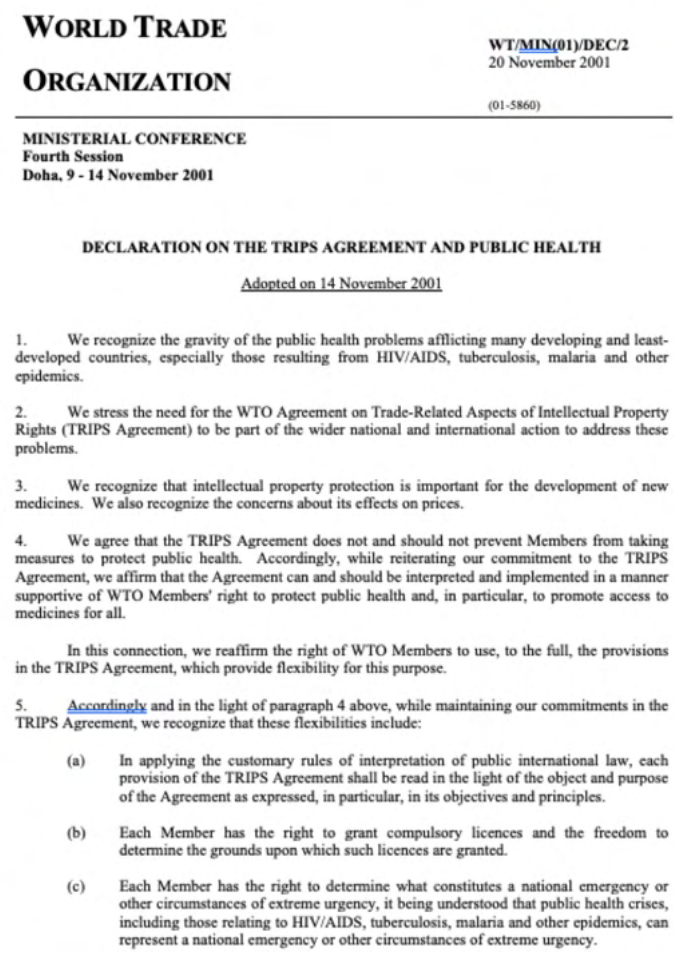
IN THE HIGH COURT OF SOUTH AFICA (TRANSVAAL PROVINCIAL DIVISION) Case number: 4183/98 In the matter between:



VS.

1999 WTO Ministerial Conference in Seattle

2001 Doha Declaration TRIPS and Public Health



WORLD TRADE ORGANIZATION

WT/MIN(01)/DEC/2
20 November 2001

(01-5860)

MINISTERIAL CONFERENCE
Fourth Session
Doha, 9 - 14 November 2001

DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH

Adopted on 14 November 2001

1. We recognize the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.

2. We stress the need for the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) to be part of the wider national and international action to address these problems.

3. We recognize that intellectual property protection is important for the development of new medicines. We also recognize the concerns about its effects on prices.

4. We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all.

In this connection, we reaffirm the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.

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

(a) In applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles.

(b) Each Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.

(c) Each Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.

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.

2 Key TRIPS Flexibilities for A2M

- Compulsory licensing / government use
  - Use of the patent without the consent of the patent holder against the payment of a reasonable royalty. GU when gov. makes use of the patent for its own purposes
- LDC transition
  - No obligation until 2030 to grant or enforce pharmaceutical product patents

TRIPS Flexibilities 2001-2016

Zoom Out

Policy & practice

Medicine procurement and the use of flexibilities in the Agreement on Trade-Related Aspects of Intellectual Property Rights, 2001–2016

Ellen FM 't Hoen,[a] Jacquelyn Veraldi,[b] Brigit Toebes[c] & Hans V Hogerzeil[a]

Abstract Millions of people, particularly in low- and middle-income countries, lack access to effective pharmaceuticals, often because they are unaffordable. The 2001 Ministerial Conference of the World Trade Organization (WTO) adopted the Doha Declaration on the TRIPS (Trade-Related Aspects of Intellectual Property Rights) Agreement and Public Health. The declaration recognized the implications of intellectual property rights for both new medicine development and the price of medicines. The declaration outlined measures, known as TRIPS flexibilities, that WTO Members can take to ensure access to medicines for all. These measures include compulsory licensing of medicines patents and the least-developed countries pharmaceutical transition measure. The aim of this study was to document the use of TRIPS flexibilities to access lower-priced generic medicines between 2001 and 2016. Overall, 176 instances of the possible use of TRIPS flexibilities by 89 countries were identified: 100 (56.8%) involved compulsory licences or public noncommercial use licences and 40 (22.7%) involved the least-developed countries pharmaceutical transition measure. The remainder were: 1 case of parallel importation; 3 research exceptions; and 32 non-patent-related measures. Of the 176 instances, 152 (86.4%) were implemented. They covered products for treating 14 different diseases. However, 137 (77.8%) concerned medicines for human immunodeficiency virus infection and acquired immune deficiency syndrome or related diseases. The use of TRIPS flexibilities was found to be more frequent than is commonly assumed. Given the problems faced by countries today in procuring high-priced, patented medicines, the practical, legal pathway provided by TRIPS flexibilities for accessing lower-cost generic equivalents is increasingly important.

Abstracts in عربي, 中文, Français, Русский and Español at the end of each article.

Introduction

The challenges posed by the high price of antiretroviral medicines in the late 1990s, coupled with widespread patenting of these medicines, led to efforts to ensure that the World Trade Organization's (WTO's) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) could be implemented more flexibly to allow for the procurement of low-priced medicines.[1] In 2001, a Ministerial Conference of the WTO adopted the Doha Declaration on the TRIPS Agreement and Public Health (that is, the Doha Declaration).[2] The declaration recognized both the importance of intellectual property for the development of new medicines and concerns that intellectual property rights affected medicine pricing. It lists several measures that countries can take to ensure access to medicines for all, such as the use of compulsory licensing to produce or purchase lower-priced generic medicines. Paragraph 7 of the declaration removed the obligation to grant and enforce medicine patents and data protection for WTO Members designated by the United Nations as least-developed countries, initially until 1 January 2016, this is referred to as the least-developed countries pharmaceutical transition measure. In 2002, the WTO's Council for TRIPS formally adopted a decision implementing Paragraph 7 and later extended the transition period until at least 2033.[3,4] Of the 48 countries designated least-developed countries, 36 are currently WTO Members.[5]

Compulsory licensing is the right granted by a government authority to make use of a patent during the patent term without the consent of the patent holder, for example, for the production or supply of generic medicines. According to Article 31 of TRIPS, a government can also authorize use of a patent for its own purposes: this is called public noncommercial use and is also referred to as government use. A public noncommercial use licence can be assigned either to a state agency or department or to a private entity. When a compulsory licence or public noncommercial use licence is issued, the patent holder is generally entitled to adequate remuneration for use of the patent.[6]

The extent to which countries have deployed TRIPS flexibilities, such as compulsory licences or public noncommercial use licences, for procuring medicines remains underreported. Previous studies have documented well-known and widely publicized cases of compulsory licensing, but have not examined the use of TRIPS flexibilities in procurement.[7,8] Moreover, several reports in the literature perpetuate the belief that, since 2001, the use of TRIPS flexibilities has been sporadic and limited.[9–11]

The aim of our study was to document the use of TRIPS flexibilities to gain access to lower-priced generic medicines. Although we recognized that the TRIPS Agreement offers a range of flexibilities relevant to national pharmaceutical and patenting policies, including the right of countries to define and apply patentability criteria and to refuse to grant patents for certain subject matter (e.g. plants and animals), we focused on measures that can be directly applied to the procurement and supply of medicines. The most relevant measures for increasing access to medicines were: (i) compulsory licensing (including public noncommercial use licensing); (ii) the least-developed countries pharmaceutical transition measure;

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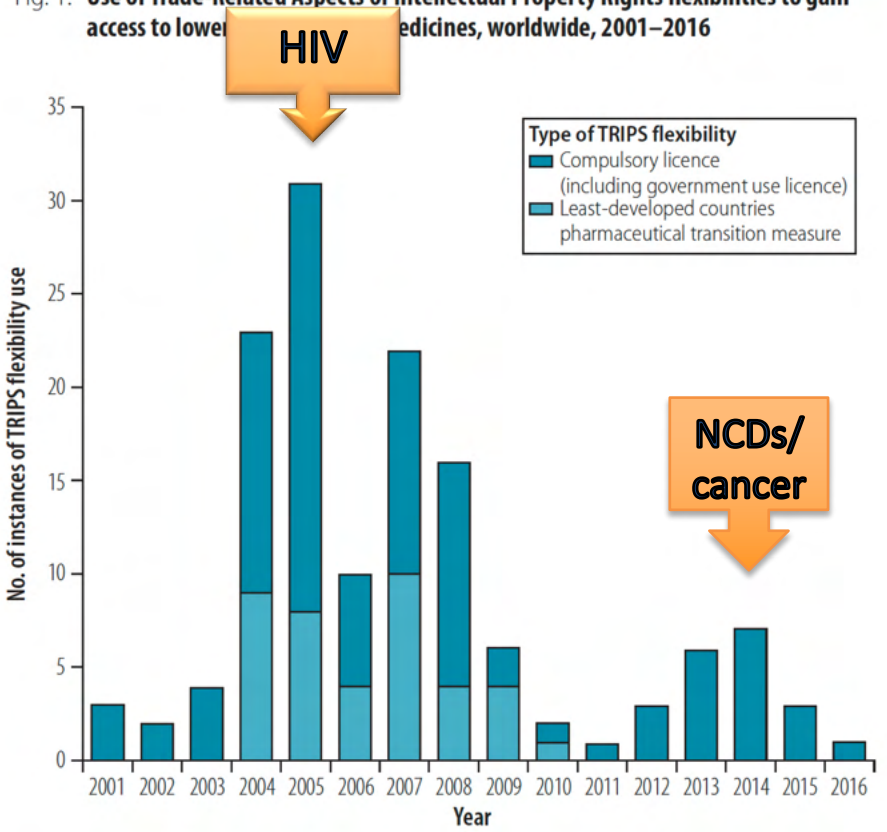
- 176 instances (89 countries) 2001-2016
- 100 (56.8%) CL/GU
- 40 (22.7) LDC non-enforcement of patents
- 1 PI
- 3 research exception
- 32 non-patent related
- 137 (78%) HIV

Fig. 1. **Use of Trade-Related Aspects of Intellectual Property Rights flexibilities to gain access to lowe edicines, worldwide, 2001–2016**



TRIPS: Trade-Related Aspects of Intellectual Property Rights (Agreement on).
Note: The least-developed countries pharmaceutical transition measure applies to World Trade Organization (WTO) Member States designated by the United Nations as least-developed countries and removes them from the obligation to grant and enforce medicine patents in accordance with Paragraph 7 of the Doha Declaration.

FM't Hoen E, Veraldi J, Toebes B, Hogerzeil HV. Medicine procurement and the use of flexibilities in the Agreement on Trade-Related Aspects of Intellectual Property Rights, 2001–2016. Bulletin of the World Health Organization. 2018 Mar 1;96(3):185. http://www.who.int/bulletin/volumes/96/3/17-199364.pdf

Use of TRIPS flex 2001-2021

TRIPS Flex		Not executed	Price red/VL/donation
CL/GU	108	22 ->	13
Par7/LDC extension	47		
Total	155		

Non-executed compulsory licensing are often a result of better price offers, voluntary licensing or donations companies have offered.

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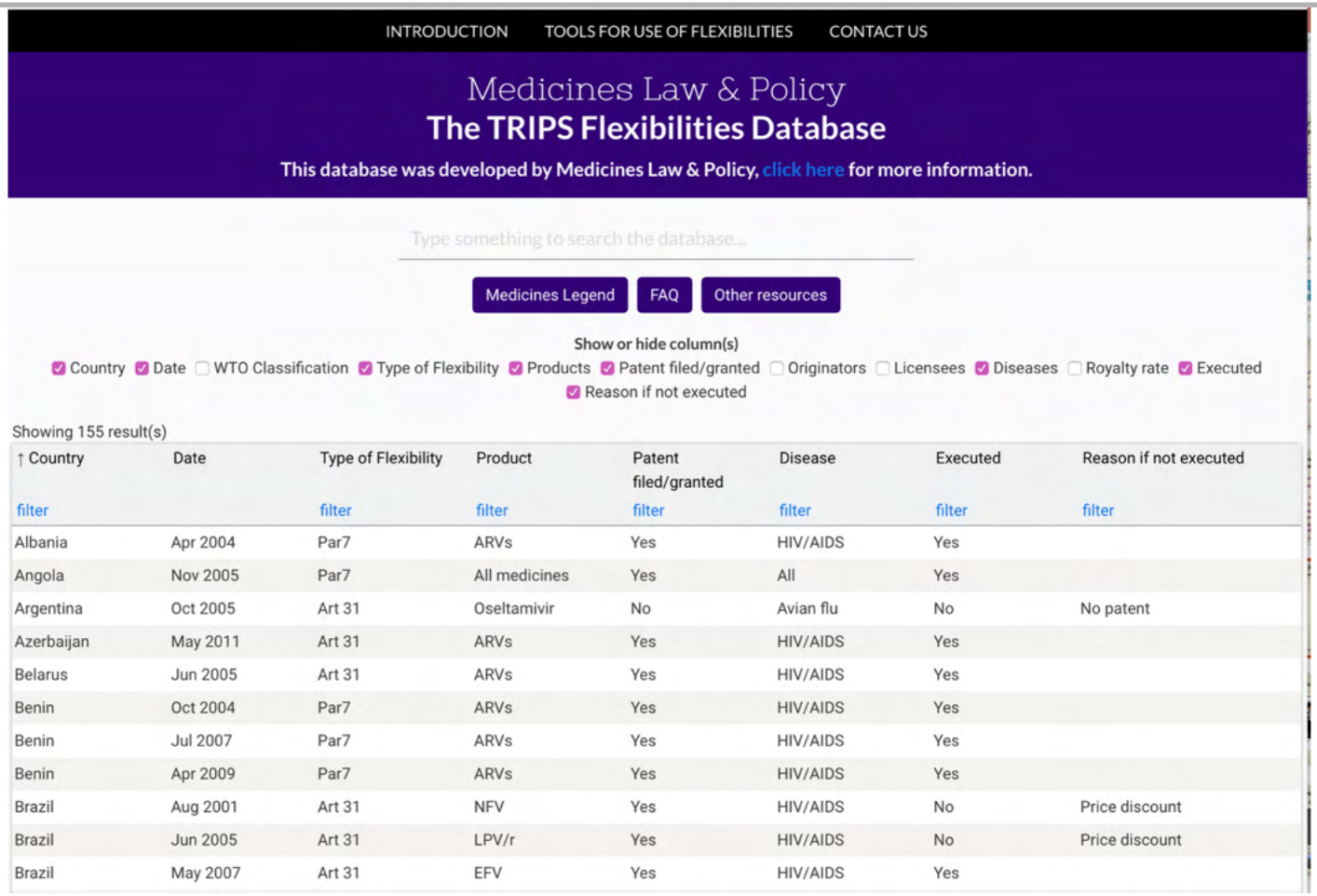
TRIPS Flexibilities Database

http://tripsflexibilities.medicineslawandpolicy.org/



INTRODUCTION TOOLS FOR USE OF FLEXIBILITIES CONTACT US

Medicines Law & Policy

The TRIPS Flexibilities Database

This database was developed by Medicines Law & Policy, click here for more information.

Type something to search the database...

Medicines Legend | FAQ | Other resources

Show or hide column(s)

☑ Country ☑ Date ☐ WTO Classification ☑ Type of Flexibility ☑ Products ☑ Patent filed/granted ☐ Originators ☐ Licensees ☑ Diseases ☐ Royalty rate ☑ Executed ☑ Reason if not executed

Showing 155 result(s)

↑ Country	Date	Type of Flexibility	Product	Patent filed/granted	Disease	Executed	Reason if not executed
filter		filter	filter	filter	filter	filter	filter
Albania	Apr 2004	Par7	ARVs	Yes	HIV/AIDS	Yes	
Angola	Nov 2005	Par7	All medicines	Yes	All	Yes	
Argentina	Oct 2005	Art 31	Oseltamivir	No	Avian flu	No	No patent
Azerbaijan	May 2011	Art 31	ARVs	Yes	HIV/AIDS	Yes	
Belarus	Jun 2005	Art 31	ARVs	Yes	HIV/AIDS	Yes	
Benin	Oct 2004	Par7	ARVs	Yes	HIV/AIDS	Yes	
Benin	Jul 2007	Par7	ARVs	Yes	HIV/AIDS	Yes	
Benin	Apr 2009	Par7	ARVs	Yes	HIV/AIDS	Yes	
Brazil	Aug 2001	Art 31	NFV	Yes	HIV/AIDS	No	Price discount
Brazil	Jun 2005	Art 31	LPV/r	Yes	HIV/AIDS	No	Price discount
Brazil	May 2007	Art 31	EFV	Yes	HIV/AIDS	Yes	

2017 Malaysia Government use licence for SOF

Govt allows cheaper versions of Hep-C drug imports

By LOH FOON FONG
foonfong@thestar.com.my

PETALING JAYA: The Cabinet has given approval for Malaysia to issue government-use licences to enable the import of generic versions of the Hepatitis C drug Sofosbuvir.

Confirming this, the Domestic Trade, Cooperatives and Consumerism Ministry said some 400,000 Hepatitis C patients in the country will be able to benefit from cheaper drugs for use in public hospitals.

According to information from the ministry, the Health Ministry tabled a Cabinet paper on the implementation of government rights under Section 84 of the Patents Act last month and that it had agreed to it.

"The Health Ministry got approval from the Cabinet on the execution of these rights," it said in response to questions from *The Star*.

The Patents Act comes under the purview of the Intellectual Property Corporation of Malaysia – known as MyIPO – under the ministry.

The government-use licence is only for drugs to be used in public health facilities.

Clinical trials are being conducted in cooperation with the Neglected Diseases Institute and an Egyptian generic company in a project to make available a generic version of Sofosbuvir, combined with another drug.

Since Sofosbuvir is patented, a government-use licence is needed to waive the monopoly right and enable the sale of generic drugs, acting as a key to affordable treatment.

Spread through blood and semen, the disease is caused by a virus that infects the liver, with many patients not even aware of having it until they discover liver damage.

In July, *The Star* had carried a front-page report that about 400,000 Malaysians were suffering from Hepatitis C but only a fraction could afford the medication, which might cost up to RM300,000 for the full course of treatment.

Malaysia is not given special pricing for drugs by pharmaceutical companies because it is considered a middle-income country.

It was reported that Gilead Science, an American research-based bio-pharmaceutical company, had announced its decision on Aug 24 to expand its HIV and Hepatitis C generic licensing agreement to Malaysia, Thailand, Ukraine and Belarus.

Local think-tank Galen Centre for Health and Social Policy chief executive officer Azrul Mohd Khalib said the granting of a Sofosbuvir voluntary licence by Gilead Sciences meant that it would be possible for lower-cost generic versions of this life-saving drug to be made available in Malaysia.

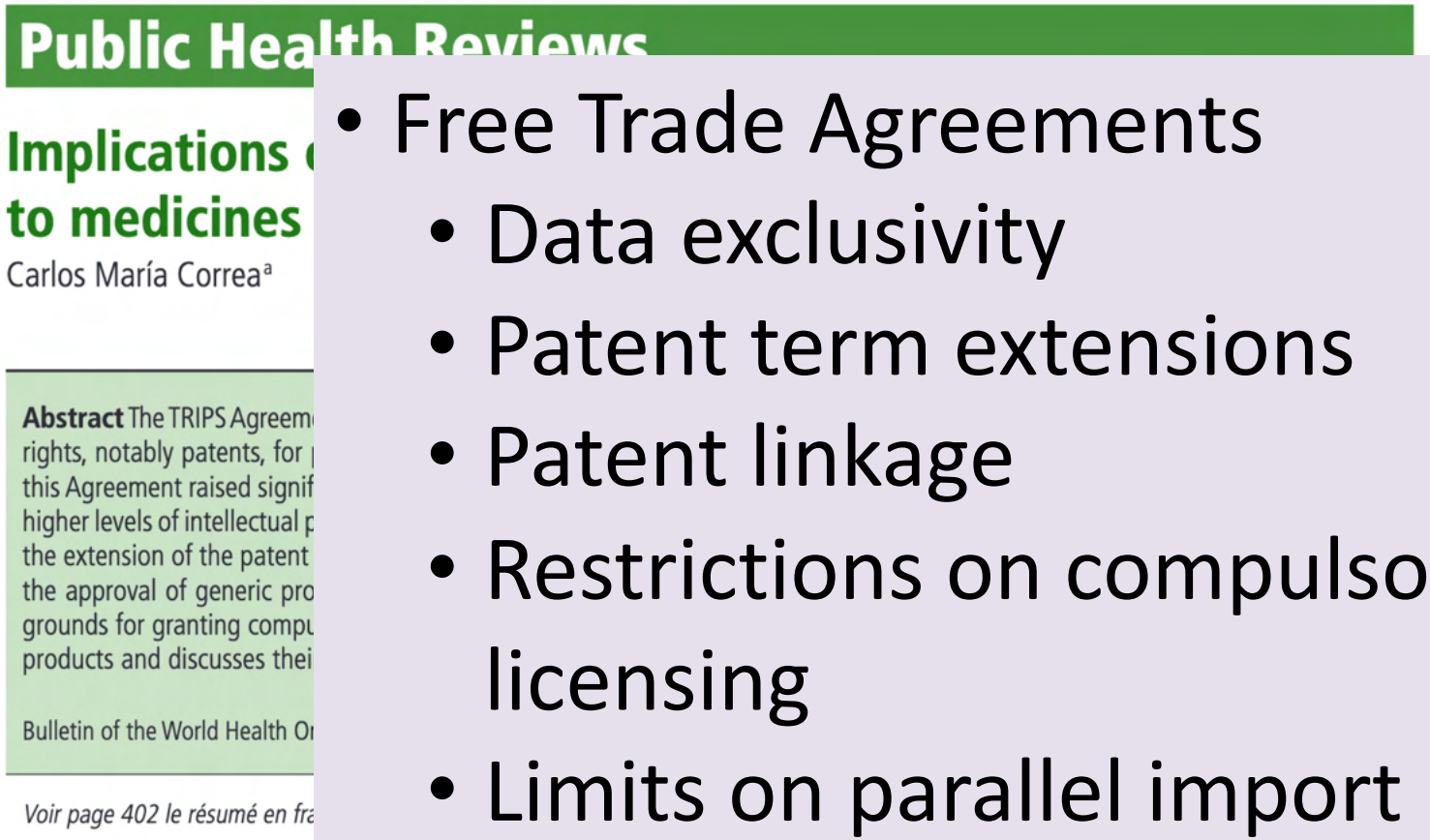
Positive Malaysian Treatment Access and Advocacy Groups director Edward Low said the Cabinet's approval of the government-use licence was a good move.

"It is a milestone in making Hepatitis C treatment accessible to Malaysians," he said.

Low also said that government-use licence was a better choice than voluntary licence as this allowed a broader option of drugs that could be used.

When contacted, the Health Ministry said it would prepare a statement on the issue soon.

Threat to TRIPS Flexibilities


Public Health Reviews

Implications
to medicines

Carlos María Correa[a]

Abstract The TRIPS Agreem
rights, notably patents, for
this Agreement raised signif
higher levels of intellectual p
the extension of the patent
the approval of generic pro
grounds for granting compu
products and discusses thei

Bulletin of the World Health O

Voir page 402 le résumé en fra

- Free Trade Agreements
  - Data exclusivity
  - Patent term extensions
  - Patent linkage
  - Restrictions on compulsory licensing
  - Limits on parallel import
- Political will

Some Legal developments with key NGO/CS role in the last 2 decades

International

- WTO: '01 WTO Doha Declaration
- WTO: '03 CL for export → '05, '17
  1st and only TRIPS amendment (31bis)
- WTO: Least developed country extension (s)
- WHO: Global Strategy and Plan of Action on IP, Innovation and Public Health
- WIPO: Development Agenda
- UN: High Level Panel on Access to Medicines -> delinkage agenda
- UNITAID: Creation of the Medicines Patent Pool

National

- '98-'01 South Africa court case
- '03 SA TAC competition commission
- '05 –India Patents Act amendment
- Patent challenges (India, Thailand, EU, etc).
- Patent law reform advocacy
- **Use of TRIPS flexibility in procurement**

Thank you!

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For background sources please visit:

www.medicineslawandpolicy.org

http://tripsflexibilities.medicineslawandpolicy.org/