

A hand holding a coin against a purple background with a white circular graphic. The hand is positioned in the lower-left quadrant, holding a small, round coin. The background is a solid purple color with a large white circular shape on the left side. The text is in white, sans-serif font.

# Chronicle of Compulsory Licenses Foretold: The Sofosbuvir Case in OECD Latin American Countries

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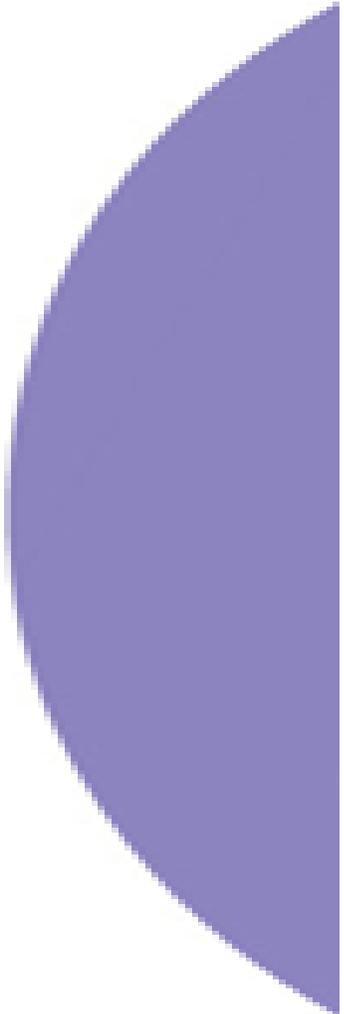
welcome

Act 1: with a little help from my  
trips

Act 2: i should have known  
better

Act 3: conclusions (let it be)



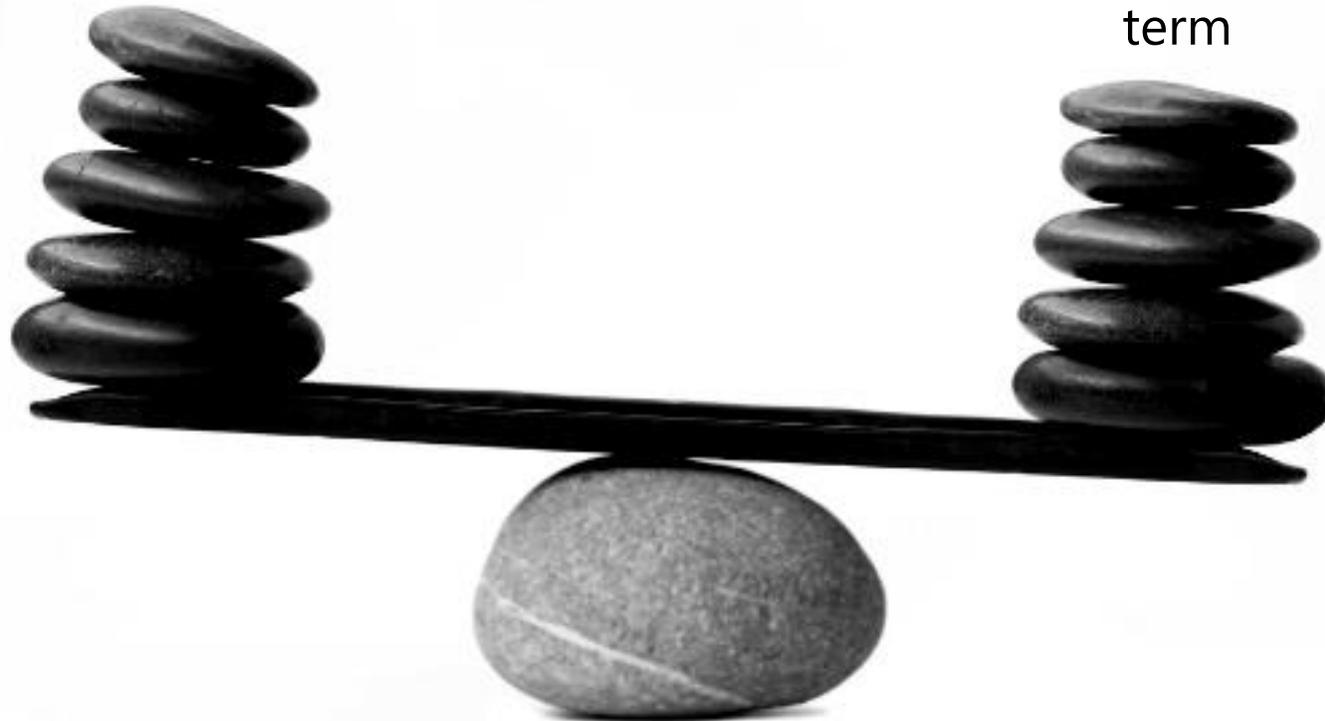


# ACT 1

# PREMISE

**Static efficiency**  
competitive prices in the  
short term

**Dinamic  
efficiency**  
Technological progress  
& innovation in the long  
term



# TRIPS

## 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;

(...)



IN CASE OF EMERGENCY  
BREAK THE GLASS



## Doha Declaration on the TRIPS and Public Health (2001)

4. We agree that the TRIPS Agreement does not and should not prevent Members from **taking measures to protect public health.** (...)
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.**

When  
a situation of  
**public interest**  
arises?



# TRIPS

## Article 8

### Principles

1. Members may, in formulating or amending their laws and regulations, adopt measures **necessary to protect public health and nutrition**, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.

# Consistency of a public interest measure with Article 8 of TRIPS

## Necessity Test (GATT)



### 1st. Weighing and balancing of the protected right

→ Assessment on the importance of the interest whose protection is sought

↪ a) Assessment on the level of protection which is sought and the contribution that the disputed measure has as to its achievement

↪ a) Assessment on the trade-restrictiveness of the disputed measure

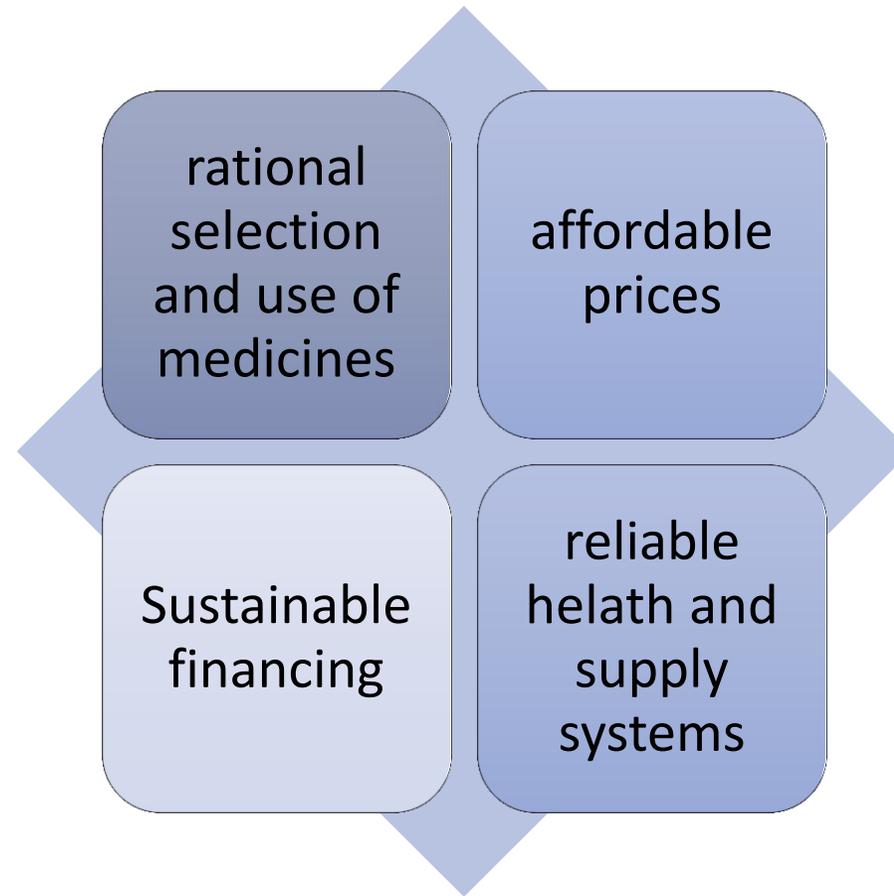
### 2nd. Least-Trade restrictive means

→ a) Verification of whether there is not any less restrictive alternative that can achieve such level of protection

↪ a) Verification of whether the found alternative is a reasonably available measure

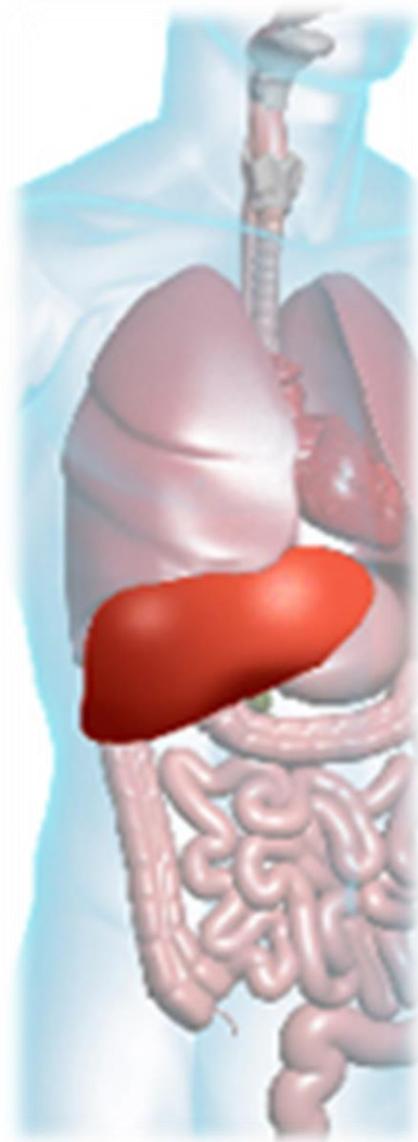
# Keydrivers for access to medical technologies

(WTO-WIPO-WHO 2012)





# ACT 2



## Hepatitis C

Liver infection caused by the hepatitis C virus, which may lead to serious health problems like liver cancer or cirrhosis



**HARVONI**<sup>®</sup>  
ledipasvir / sofosbuvir  
90 mg / 400 mg tablets

**97%**

**Overall cure rate across three HARVONI Phase 3 trials<sup>1,4-6</sup>**

(n=1042/1079; ION-1, -2, -3)





## Sofosbuvir case

Request facts (October 2015)

# Request for CL in Colombia

(Decision 486 of Andean Community)

Requesting antivirals for treatment of hep C, including sofosbuvir, other 12 active principles and any other principle developed in the future.



2. issuance of CL

3. entrance of competitors

- Cost of the treatment: US \$ 1000 per tablet (one daily tablet for approx. 12 weeks). Generic versions could imply a treatment cost of only US \$ 300 .

Previous experience:

Declaration of public interest for (1) lopinavir-ritonavir and

(2) imatinib

But no compulsory licences have been granted

- The cost threatens the **financial sustainability of the social security scheme.**

Status: PENDING DECISION



## Reasons for the decision

### Request for Clin Chile

1. declaration of reasons of public health

2. issuance of CL

- Request facts (March 2017)
  - 19.000 patients enrolled in the Public Health System, however the current demand is 8 times more complicated (Law 19.000) and that urgently require antiviral treatment (approx. 300 people).
  - Chile could get it for lesser than US \$ 500 per the
  - Since 2015, Chile acquires sofosbuvir/ledipasvir for approx. US \$ 10,000 per treatment, due to
  - More patients would be treated, while, at the same time, the burden of the state budget would decrease quote from Gilead's distributor: sofosbuvir/velpatasvir for US \$ 5,100 and sofosbuvir/ledipasvir for US \$ 8,100.
- Generic versions could imply a treatment cost of only US \$ 350 (March 2018)
- Undermining of the financial sustainability of the health sector.

Status: APPROVED (March 2018)



## LET'S ANALYZE IT

### 1. Balance of the protected right

-a. Financial sustainability of the social security scheme.

b. There is an idea of the sought level of contribution, although no data on the available budget.

c. CL have a direct restrictive effect on patent rights. There is not a proper identification of possible affected patents.

### Measures

No mention on the exhaustion of other possible measures to be pursued



July 2017

Colombia was included in a centralized purchasing mechanism developed by the Pan American Health Organization (PAHO)

**Achieved savings:**

**80%**



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## 1. Balance of the protected right

-a. Increase of treated patients & financial sustainability of the social security scheme.

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b. There is an idea of the sought level of contribution, although no data on the available budget.

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c. CL have a direct restrictive effect on patent rights. There is not a proper identification of possible affected patents.

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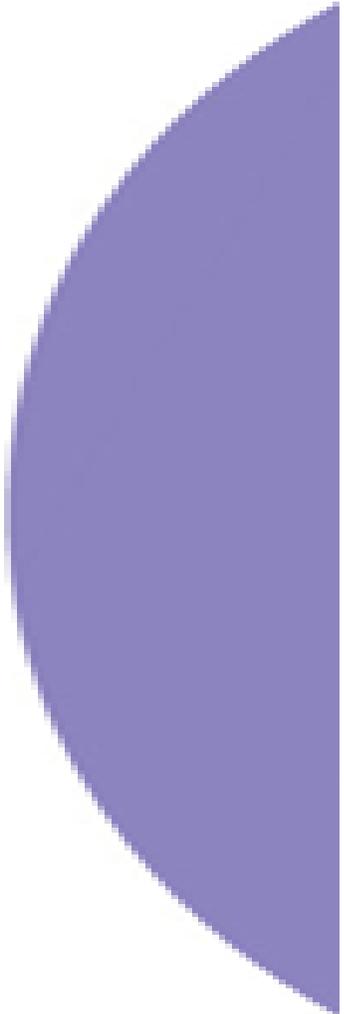


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## 2. Less restrictive measures

Reference to negotiations to obtain better prices, having achieved savings for 81%, although apparently this is not enough.

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# ACT 3

## CONCLUSIONS (LET IT BE)

- a. When compulsory licenses are used as instruments to pursue government financial sustainability (administrative efficiency), there is a need for the identification of less restrictive alternatives.
- b. The official measure adopted by Chile could be taken as legitimate, although there are still some details that should be cleared. On the other hand, the request made in Colombia would not be duly justified.