

# Public health system increasing costs due to the extension of drug patents terms

Dr. Julia Paranhos  
Associate Professor  
Federal University of Rio de Janeiro

## CONTEXT

### 1 PATENT LAW

The Sole Paragraph of Art. 40 of the Industrial Property Law (LPI, nº 9,279 / 1996): patents are valid for at least 10 years from the date of the grant

### 2 BACKLOG

INPI: high backlog of patent applications pending a final decision - 13 years to pharma patents (INPI, 2018)

### 3 PHARMA

92.2% of pharma patents granted in Brazil (1997-2018) will be valid for more than 20 years (Mercadante, 2019)





## RESEARCH QUESTION

What is the potential additional cost to the Brazilian Unified Health System (SUS) caused by the extension of patent term conferred by the Sole Paragraph of Article 40 of the Industrial Property Law?



# METHODOLOGY

Selection of drugs from the Federal Government public procurement website:

- 1) high costs drugs
- 2) patent situation

**A**

**GRANTED  
PATENTS**

Will be valid for more than 20 years

**B**

**PENDING  
APPLICATIONS**

If granted, will be valid for more than 20 years

**C**

**MAILBOX  
PATENTS**

Already granted, will be valid for more than 20 years if the Sole Paragraph of Art. 229 is reformed

**TRIPS  
Agreement**



# DRUGS AND PATENTS ANALYSED

Groups / Drugs	Concentration	Company	Patent	Extension (in years)
<b>A</b>	golimumabe	Janssen-Cilag	PI0113110	6.6
	daclatasvir	Bristol-Myers Squibb	PI0716483	1.2
	dasatinibe	Bristol-Myers Squibb	PI0009721	8.6
	nilotinibe	Novartis	PI0312464	4.0
<b>B</b>	certolizumabe pegol	AstraZeneca	PI0106682	7.7
	darunavir	Janssen-Cilag	PI0311176	5.8
	sofosbuvir	Gilead	PI0809654	0.9
<b>C</b>	adalimumabe	AbbVie	PI9707379	3.0
	eculizumabe	Alexion	PI9507594	4.5

Group B  
from  
18/02/19

Total MoH expenditure (2014-2018): R\$ 10.6 bi (US\$ 2.8 bi)

Average annual expenditure: R\$ 1.9 bi (US\$ 521 mi; 1.5% of SUS budget in 2018)

Exchange rate: R\$ 3.73 (BCB, 18/02/2019)

**Total MoH expenditure  
(in the periods of patents extension)  
R\$ 6.8 bi (US\$ 1.8 bi)**



# **MORE ECONOMICAL ALTERNATIVES**

**Actual & hypothetical**

# ACTUAL PRICE REDUCTION

based on generics prices in the international market

A

daclatasvir



99.1%

dasatinibe



77.1%

B

darunavir



58.1%

sofosbuvir



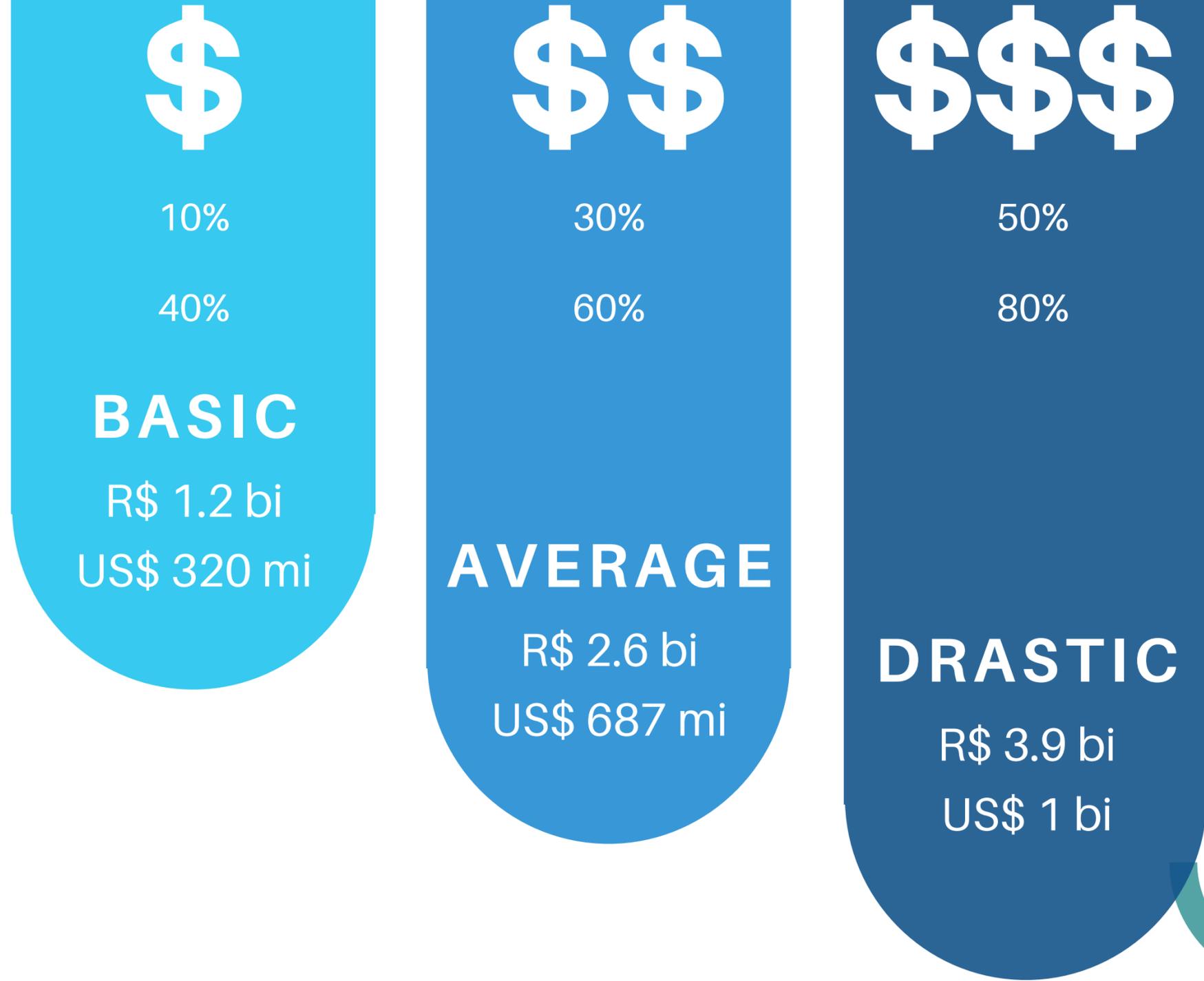
98.9 %

**4 drugs**

**75.5%**

**R\$ 1.2 bi**  
**(US\$ 311 mi)**



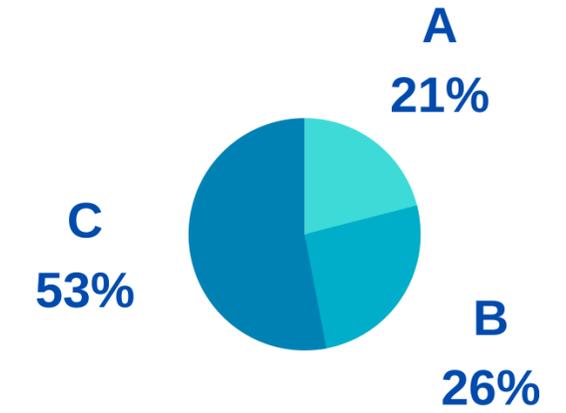


BIOSIMILARS  
GENERICS

**9 drugs**



**57.4% OFF**



# HYPOTHETICAL PRICE REDUCTION

based on market standards

# COMPLEMENTARY RECOMMENDATIONS



## MoH

Should be more proactive in requesting the fast track of drug patent applications that may be extended



## INPI

Financial autonomy to constitute the required personnel

## SUPREME COURT

The patent term extension clause conferred by the Sole Paragraph of Art. 40 of the LPI should be revoked



At least, it should be clear that it excludes mailbox patents, which represent the largest spending group in this sample



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## CONTACT

### Coordination:

Julia Paranhos  
juliaparanhos@ie.ufrj.br



## TEAM

Lia Hasenclever (UFRJ; UCAM-Campos)  
Eduardo Mercadante (UFRJ; LSE)  
Thiago Azevedo (UFRJ)



## TRANSPARENCY

Funded by Libbs Farmacêutica Ltda.  
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