

PUBLIC HEALTH SYSTEM INCREASING COSTS DUE TO THE EXTENSION OF DRUG PATENTS TERMS

Executive Summary
2019

Researchers

Julia Paranhos
Lia Hasenclever
Eduardo Mercadante
Thiago Azevedo



CONTEXT

Brazil's patent law has adopted provisions that go beyond the international standards, as the Sole Paragraph of Art. 40 of the Industrial Property Law (LPI, nº 9,279 / 1996). This provision expands the protection of intellectual property rights by ensuring that patents are valid for at least 10 years from the date of the grant. It should be noted that the National Institute of Industrial Property (INPI) has a high backlog of patent applications pending a final decision, which causes the extension of the vast majority of pharmaceutical patents due to delays in the examination. Given the strong provisional rights related to pharmaceutical patent applications, this will delay the entrance of competitors in the market. Therefore, the minimum term clause has perverse effects in competition in the sector and in public and private health budgets.

OBJECTIVE

This study analyzed the potential additional costs for the Unified Health System (SUS) due to the extension of the patent term of nine drugs, divided into three groups:

- A** Granted patents that will be valid for more than 20 years
- B** Applications that, if granted, will be valid for more than 20 years
- C** Granted mailbox patents that will be valid for more than 20 years if the Sole Paragraph of Art. 229 is reformed.

Based on public procurement data from 2014 to 2018, we found that the Logistics Department of the Ministry of Health (MoH) spent R\$ 10.6 bi (US\$ 2.8 billion) on these nine drugs, with an average annual expenditure of R\$ 1.9 bi (US\$ 521 million).

DATA

We calculated that during the periods of patent extension, the MoH would spend R\$ 6.8 bi (US\$ 1.8 billion) on these purchases.

RESULTS

Four alternative procurement scenarios were estimated, which would be possible without the term extension clause. The best scenario estimates a **57.4%** of savings in the purchase of the nine drugs during the periods of the patent extension.

The first alternative is based on real generic prices found in the international market for four drugs, which alone could already reduce the total spending in the respective extension periods by **R\$ 1.2 bi** (US\$ 311 million) (**75.5%**). Furthermore, we estimated three hypothetical levels of price reduction based on market standards. The most basic reduction would avoid an expense of **R\$ 1.2 bi** (US\$ 320 million). The average reduction would prevent the spending of **R\$ 2.6 bi** (US\$ 687 million). The drastic reduction would allow the MoH to save **R\$ 3.9 bi** (US\$ 1 billion), more than half of the total spending in the period.

TABLE: TOTAL AND ANNUAL EXPENDITURE AND COST IN THE PERIODS OF PATENT EXTENSION (US\$ MILLION)

Group	Drugs	Annual average expenditure	Total expenditure 2014-2018	Annual cost during extension	Total cost during extension
A	golimumabe	29.1	145.3	14.5	96.2
	daclatasvir	29.9	182.1	23.9	28.0
	dasatinibe	8.9	82.4	7.2	61.7
	nilotinibe	10.6	53.0	8.5	33.9
	Total	78.5	462.7	54.1	219.8
B	certolizumabe pegol	9.1	45.4	4.5	35.0
	darunavir	33.7	232.4	27.0	155.7
	sofosbuvir	116.1	464.4	92.9	83.7
	Total	158.9	742.3	124.4	274.4
TOTAL A + B		237.4	1,205.0	178.5	494.2
C	adalimumabe	165.3	1,018.3	82.7	265.7
	eculizumabe	118.9	627.8	59.5	294.2
	Total	284.2	1,646.1	142.1	559.8
TOTAL A + B + C		521.7	2,851.1	320.6	1,054.0

Source: Prepared by IE/UFRJ, based on data from the Federal Government (2019a).

*average exchange rate in 18/02/2019 of R\$ 3.73 (BCB, 2019)



RECOMMENDATIONS

MoH

In view of these findings, three complementary recommendations are made.

First, the MoH should be more proactive in requesting the fast track of drug patent applications that may be extended.

Supreme
Court

Second, the patent term extension clause conferred by the Sole Paragraph of Art. 40 of the LPI should be revoked, or at least it should be clear that it excludes mailbox patents, which represent the largest spending group in this sample.

INPI

Finally, there is an immediate need for institutional strengthening of the patent office, guaranteeing its financial autonomy to constitute the necessary staff, thus enhancing the quality, efficiency and independence of the patent exams and rendering patent term extensions the exception, not the rule.

More information in Paranhos, J.; Mercadante, E.; Hasenclever, L. O custo para o SUS da extensão da vigência de patentes de medicamentos. *Cadernos de Saúde Pública*, forthcoming.



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.
The content is the authors
responsibilities