



The Patent Paradox in Brazil

IMPLICATIONS FOR
PURCHASES OF
MEDICINES BY THE
PUBLIC HEALTH SYSTEM

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1.

The context: what is the patent paradox and how does it operate in Brazil?

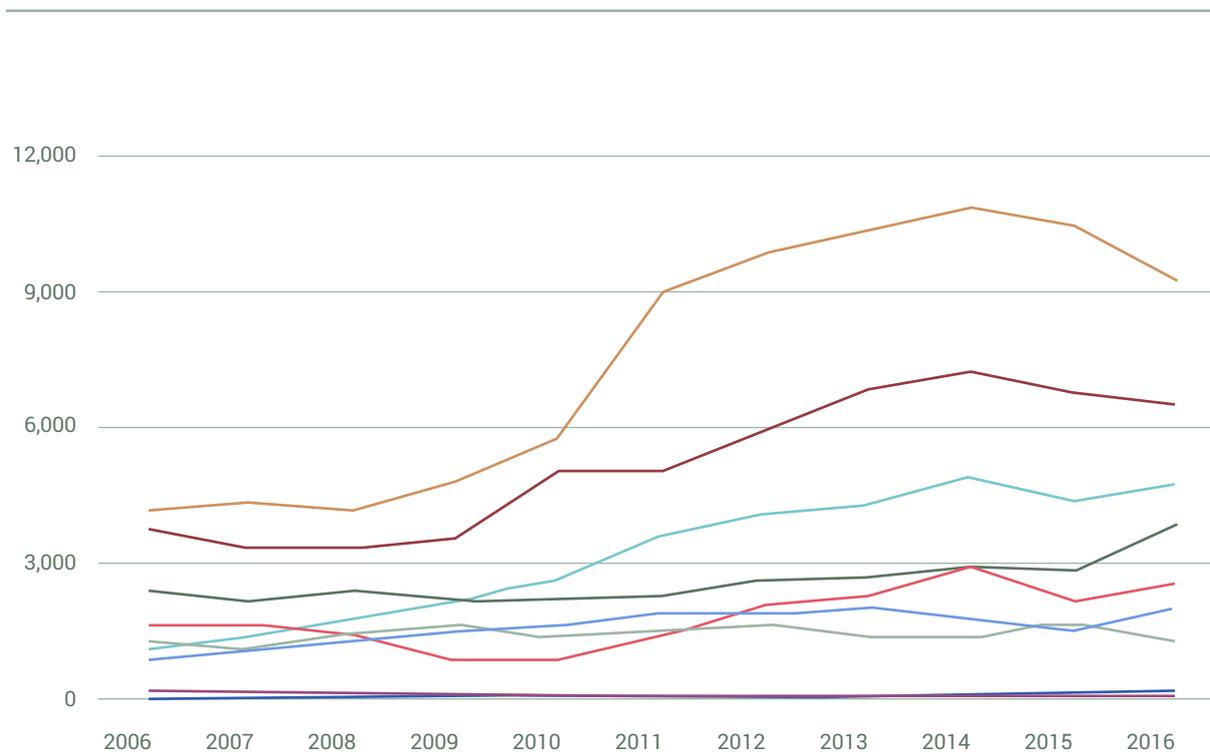
1. The context: what is the patent paradox and how does it operate in Brazil?

The patent system was allegedly designed to allow for recovering of investment in research and development (R&D) of a new product through the selling of the product under exclusivity for a period of time. However, linking the price of the end product to the costs of R&D has been shown to hinder both innovation and access.¹

Several studies have related high prices of medicines with the monopoly situation established by the patent system and other monopoly rights (such as data exclusivity).² It has been shown that the existence of a patent can lead to high prices due to the market condition in which one producer can operate with exclusivity. In the absence of competition, a producer can virtually charge any price for its product, even when it is considered essential for human life and health, such as medicines and other health technologies. Competition can promote significant price reduction and increase access.³

Brazil is frequently pointed to as one of the countries in which fewer pharmaceutical patents are granted.⁴ Some studies about patenting in the pharmaceutical sector comparing the number of patents granted in different countries have been conducted.⁵ Figure 1 illustrates the difference between countries of the top 10 patent offices in relation to patent grants in the pharmaceutical sector, compared to Brazil (in the bottom line).

Figure 1 - Patent grants by technology – pharmaceuticals – 10 top patent offices* – 2006-2016



Legend:

- Brazil/16 - Pharmaceuticals
- Canada/16 - Pharmaceuticals
- China/16 - Pharmaceuticals
- European Patent Office/16 - Pharmaceuticals
- Germany/16 - Pharmaceuticals
- Japan/16 - Pharmaceuticals
- Republic of Korea/16 - Pharmaceuticals
- Russian Federation/16 - Pharmaceuticals
- United States of America/16 - Pharmaceuticals

Source: WIPO Statistics Database.* India is amongst the top 10 patent offices, but no country data was provided for patent grants for pharmaceuticals.

Another example is a study conducted by Correa et al. (2011) comparing pharmaceutical patents granted in Argentina, Brazil, Colombia, India and South Africa. It shows that in Argentina, 951 pharmaceutical patents were granted between 2000-2007; in Brazil, 278 patents were granted between 2003-2008; in India 2,347 from 2005-2008; and in South Africa, 2,442 patents were registered in 2008 alone.⁶

There can be a number of reasons why there are fewer patents granted in Brazil. That includes the high number of applications that were withdrawn or abandoned before they had any substantive examination in the country. For example, a recent study by Sampat and Shadlen (2017)⁷ analysed 2,964 pharmaceutical patent applications classified by the authors as “secondary”. The study revealed that about 60% were withdrawn or abandoned before examination in Brazil, in comparison to 27% in India for example, concluding that it is withdrawal, and not

rejection, that is the main explanation for Brazil's low grant rate. A recent report by WIPO⁸ leads to a similar conclusion, as illustrated in Figure 2 below.

Figure 2 - Distribution of patent examination outcomes (all sectors) – Brazil – 2012-14 / 2014-16



Source: WIPO, World Intellectual Property Indicators, 2017, p. 22.

Nevertheless, the fact that there is a low number of pharmaceutical patents granted in the country could lead to the conclusion that medicines can be bought under competition (recalling that Brazil does not grant data exclusivity for medicines of human use) and that the prices would be low. However, many medicines in Brazil are bought exclusively from one producer and usually at high prices.

The situation of few granted patents, but many purchases under exclusivity due to absence of competition, which can lead to higher prices, is what we are calling the 'patent paradox in Brazil'.

In the absence of granted patents for pharmaceuticals, what are the factors that lead to the situation of no competition and high prices in Brazil? This is the question that we, at the accessibsa project, aim to answer with a study currently being conducted.

The objective of the study is to conduct a comprehensive data gathering and analysis of purchases of medicines by the Brazilian Ministry of Health (MoH) from 2005 to 2016. The medicines included in the scope of the study are those that had only one supplier in the Brazilian market in the year 2016. We will look at the type of tendering that was applied to each purchase, the number of producers with market authorisation in the country, the patent status of each product and compare Brazilian prices with prices in the international market to examine how the patent paradox operates in Brazil and its implications for purchase of medicines by the Brazilian public health system - Unified Health System (SUS).

2.

The problem for the implementation of public policies of access to medicines: no granted patents, but many monopolies (and high prices)

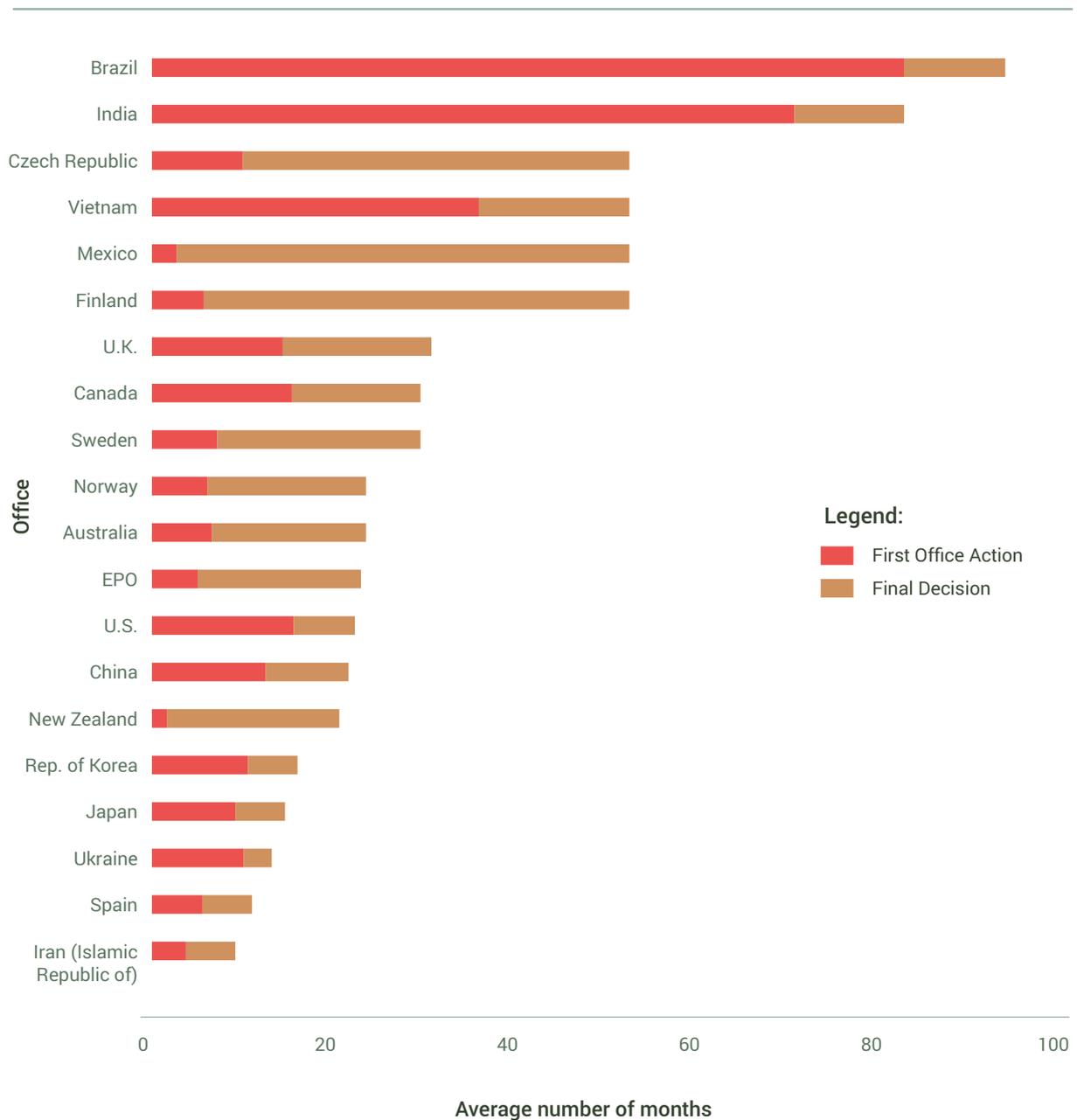
2. The problem for the implementation of public policies of access to medicines: no granted patents, but many monopolies (and high prices)

There are many factors that can lead to the existence of only one supplier of a pharmaceutical product in a given country. One main factor is related to the dynamic of the patent system. Even in the absence of granted patents, the patent system can create *de facto* monopoly, that is the situation in which there is no patent granted in the country for a given product, but it is “subject to patent protection” due to a patent application pending examination. That situation generates “legal uncertainty” around the patent status of a medicine due to the existence of pending applications⁹ and the possibility of having to pay compensation in case the patent gets granted in the future.

According to the Brazilian patent law (Law 9.279/96, article 44), in case the patent is granted, the patent holder has the right to obtain compensation for improper exploitation of the object of the patent, including that which occurs between the date of publication of the application and the date of granting of the patent. Article 208 specifies, “Compensation will be determined by the benefits that the injured party would have gained had the violation not occurred”. And Articles 209 and 2010 specify criteria for compensation, including losses and damages, and more specifically loss of profits. It should be noted that other national laws determine only the payment of royalties during pendency time.¹⁰

The situation is aggravated in the Brazilian context due to the very high average time between the filing of a patent application and its examination. Recent data from WIPO shows that Brazil is the country with highest average pendency time (95.4 months), as shown in Figure 3.

Figure 3 - Average pendency times for first office action and final decision at selected patent offices (all sectors), 2016.



Source: WIPO, World Intellectual Property Indicators, 2017, p. 19.

Specifically for the pharmaceutical sector, a study analysing 278 pharmaceutical patents granted in Brazil from 2003 to 2008 found that more than 50% of pharmaceutical patent applications took at least 8 years to be granted and around 25% took more than 10 years.¹¹

This dynamic of the patent system is not specific to Brazil but rather a reality of how pharmaceutical companies operate to maximise exclusivity over their

products, through the so called 'life-cycle management' by pharmaceutical companies or 'evergreening' by its critics. This situation increases the total number of patent applications to be processed by the patent offices and increases the legal uncertainty around the patentability of a drug.

Evergreening strategies are those adopted to extend the monopoly over existing products, blocking the entry of generic competitors in the market.¹² One such strategy is the presentation of several patent applications around one product after the application related to the base compound ('primary' or 'main' patent). These applications might include claims such as formulations, combinations, dosage, polymorphs, selection patents, analogy processes, prodrugs, method of treatment and use (including second medical use),¹³ affecting the life cycle of a product in the market. According to Kapczynski et al. (2012), those applications are called 'secondary' "because they are assumed to come later in the sequence of innovation, and to offer less robust protection than a chemical compound claim" (page 1).

There is a general concern that secondary patents are not bringing any innovation, even incremental, but instead play a role in blocking the entry of competitors in the market.¹⁴ As an example, a study conducted in Brazil on HIV/AIDS identified 447 patent applications for 20 ARVs, an average of 22 applications per each medicine. Around 25% of the applications were abandoned for some reason during the administrative process, and were never analysed for their merits. This was used by the author as an indicator of the low importance of the patent and of its use to generate uncertainty and block competition.¹⁵

This dynamic of the patent system creates a situation that interferes with the purchase of medicines and health products in Brazil, i.e. there are products subject to patent protection by several patent applications with different statuses at a given time, such as granted, rejected, pending or abandoned/withdrawn. In the absence of granted patents, the applications that are still waiting examination ('pending patent applications') can generate legal uncertainty around the patent status of a product, blocking competition.

In the problem that we are addressing, that means that during pendency time, purchases of medicines by the public sector are made without tendering and exclusively from one supplier (monopoly) even in the absence of a granted patent or other monopoly rights. The lack of competition can result in high prices.

Even if there could be legal production or import of a generic version of the medicine during the pendency time, pending patent applications can be used to produce a monopoly situation for a medicine from the supply side. This is despite generic alternatives being available in the international market. Pending applications can be used by pharmaceutical companies to create pressure against the procurement or local production of generic versions, especially in the case of purchases by the public sector. The case studies below illustrate this situation.

3.

Case studies: how the paradox operates in practice

The Patent Paradox in Brazil:

IMPLICATIONS FOR PURCHASES
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HEALTH SYSTEM

3. Case studies: how the paradox operates in practice

Data from the HIV/AIDS and Hepatitis C fields can be used to illustrate the patent paradox in Brazil. In 2015, out of the 19 ARVs used in Brazil, 13 were bought exclusively from one producer. Out of those 13, preliminary data shows that only 2 have a primary patent granted in the country; 7 have only secondary patents granted and the other 4 have patent applications pending analysis, 2 of which are only secondary patents applications. Out of the 3 new direct active antivirals (DAAs) used in the treatment of Hepatitis C, all 3 are being bought in a monopoly, despite not having any patent granted in the country (Figure 4).

Figure 4 - Patent status and purchases of ARVs and DAAs by the public sector in Brazil – December 2015

ARV/DAA	Purchase in monopoly situation? (a)	Primary patent granted? (b)	Secondary patent granted? (b)	Pending patent applications? (b)
Abacavir	Yes	No	Yes (combination)	Yes (secondary, combination)
Atazanavir	No (generic production under voluntary license)	Yes	No	Yes (secondary, derivative)
Darunavir	Yes	No (granted, but abandoned)	No	Yes (secondary, process and combination)

ARV/DAA	Purchase in monopoly situation? (a)	Primary patent granted? (b)	Secondary patent granted? (b)	Pending patent applications? (b)
Didanosine	Yes	No (granted, but expired)	Yes (formulation)	No
Efavirenz	No (generic production under compulsory license)	Yes	Yes (formulation)	Yes (formulation and combination)
Enfuvirtide	Yes	No	No	Yes (secondary, formulation)
Etravirine	Yes	Yes	No	Yes (secondary, formulation and derivatives)
Fosamprenavir	Yes	No	Yes (formulation and derivative)	No
Lamivudine	No	No	Yes (formulation and combination)	Yes (secondary, combination)
Lopinavir/r	Yes	Yes	Yes (combination)	Yes (secondary, formulation)
Maraviroc	Yes	No	No	Yes (primary)
Nevirapine	No	No	No	No
Raltegravir	Yes	No	No	Yes (primary)
Ritonavir	Yes	No	Yes (combination)	Yes

ARV/DAA	Purchase in monopoly situation? (a)	Primary patent granted? (b)	Secondary patent granted? (b)	Pending patent applications? (b)
Saquinavir	Yes	No	Yes (formulation and combination)	Yes (secondary, formulation)
Stavudine	No	No	No	No
Tenofovir	No	No	No	Yes (secondary, formulation and combination)
Tipranavir	Yes	No	Yes (formulation)	Yes (primary)
Zidovudine	Yes	No	Yes (formulation and combination)	Yes (secondary, derivatives)
Sofosbuvir	Yes	No	No	Yes
Daclatasvir	Yes	No	No	Yes
Simeprevir	Yes	No	No	Yes

Sources: a) Brazilian Ministry of Health/DLOG, through Access to Information Act, b) Patent status initially developed by GTPI/ABIA and lent to the authors.

Additionally, the case studies presented below further reveal different effects of legal uncertainty created by pending patent applications on the public purchase and local production of medicines in Brazil. These cases exemplify a broader scenario that we aim to fully investigate.

3.1. Tenofovir – no patent, many years of *de facto* monopoly and high prices

The antiretroviral (ARV) tenofovir disoproxil fumarate (TDF) was incorporated by the Brazilian public health system in 2003. It was commercialised, with exclusivity, by the American company Gilead until 2010, when a Brazilian generic version started supplying to the government. The first generic version of TDF was available in the international market in 2006.¹⁶

The first patent application related to TDF in Brazil was presented by Gilead in 1998 for the fumarate salt of the pro-drug (PI9811045-4), a secondary patent application not covering the base compound. In 2005, public manufacturer Farmanguinhos/Fiocruz presented a pre-grant opposition challenging the patentability of TDF in Brazil. In 2006, civil society organisations also presented patent oppositions in Brazil, following the experience of civil society organisations in India that were also challenging secondary patents applications around tenofovir.¹⁷

In 2008/2009, the Brazilian patent office (INPI) issued its first and its final decision (after administrative appeal) rejecting the patent. It should be mentioned that Gilead challenged that decision in court, and that the judicial case only ended in 2015.¹⁸ The first generic version of the medicine was available in the country in 2010, being locally produced by a public laboratory.

During the time in which there was 'legal uncertainty' on the patent status of TDF in Brazil due to pending patent applications (even if it was a 'secondary patent'), Gilead enjoyed a *de facto* monopoly in public procurements.

Gilead is also pursuing other evergreening strategies around tenofovir, such as presenting a new patent application for a fixed-dosed combination (FDC) covering TDF+emtricitabine (truvada®).¹⁹ The application was presented by Gilead in 2004 and was recently rejected by the Brazilian patent office in January 2017, following patent oppositions presented by civil society in 2010 and 2016 (PI0406760-6; WO/2004/064845). Gilead filed an administrative appeal in April 2017, which is still pending a decision.²⁰ Meanwhile, the Brazilian MoH just concluded the first purchase of 3.6 million pills of truvada® with exclusivity from Gilead at the cost of USD 0.75 per pill,²¹ even though there are generic versions available at the international market at the price of USD 0.13.²² If Brazil had taken the decision to buy the generic version of the medicine (as there is no patent granted in the country), it could have saved more than USD 2.2 million on that purchase alone.

The tenofovir case is indicative of different strategies adopted by pharmaceutical companies within the patent system to be able to operate with exclusivity in the market, blocking generic competition and price reductions even in the absence of granted patents.

3.2. Darunavir – primary patent granted and abandoned by the company, who uses pending secondary patent applications to block generic competition

The HIV/AIDS medicine darunavir is another example of how pending patent applications have been used to block competition in Brazil. The first patent application related to the darunavir base compound (PI9607625-9; WO/1996/28465) was presented in Brazil in 1996. This patent was granted in 2007 and was abandoned in 2011, due to the lack of payment of annual fees.²³ In total, 18 patent applications related to darunavir were initially identified in Brazil, of which 9 are related to the compound and formulations, 5 are related to intermediaries and 4 to combinations. 9 of the 18 applications have already been rejected or abandoned/withdrawn and the other 9 are still pending examination by the patent office. The pending applications are deemed to be secondary product or process applications, according to a study conducted by GTPI, a group of Brazilian civil society organisations active in the subject.²⁴

Darunavir was incorporated at the Brazilian public health system in 2008. Since then it has been bought with exclusivity from Janssen-Cilag (except in 2016), even in the absence of any granted patent since 2011, when the patent was abandoned by the company. It is one of the most expensive ARVs. In 2016, it was used by about 14,500 persons in Brazil.²⁵ In 2017, it was as a price of USD 2.42 per pill (600mg),²⁶ while there are WHO pre-qualified generic versions available at the international market at a price of USD 0.90 (600mg).²⁷ If the generic version was being bought, **considering only the volume bought in 2017, there could be savings of more than USD 27.6 million.**

In 2015, Mercosur countries launched a joint mechanism of procurement of selected high cost medicines, which includes the possibility of procurement from WHO prequalified generic producers. Darunavir was one of the medicines included in the procurement list. Data from the Brazilian MoH shows that in 2016 the medicine was partially bought from Janssen, at the price of BRL 9.60 (USD 2.75), and partially from Aurobindo through PAHO/WHO, at the price of BRL 4.34 (USD 1.24).²⁸ However, in 2017 it was bought again only from Janssen under a modality of public purchase without competition.²⁹ According to a letter from GTPI,³⁰ Janssen seems to be pressuring the Brazilian MoH not to buy any generic versions with the argument that the medicine is subject to patent protection in Brazil.

The case study of darunavir shows another way that pending patent applications can be used by pharmaceutical companies to block generic competition. The patent for the darunavir compound was granted in Brazil but abandoned by the company. Even so, Janssen seems to be pressurising the Brazilian MoH against the use of other strategies that could lead to generic competition based on the legal uncertainty generated by several (secondary) patent applications waiting examination by the patent office.

3.3. Sofosbuvir – breakthrough medicine and high cost *de facto* monopoly treatment

The breakthrough medicine for the treatment of Hepatitis C sofosbuvir is another example of how pending patent applications generate *de facto* monopoly in Brazil. We could preliminarily identify 15 patent applications related to sofosbuvir in Brazil, the oldest dating from 2001. All the patents' applications related to sofosbuvir in Brazil are still awaiting examination³¹ and therefore no patent has been granted in the country to date. Civil society organisations and public laboratory Farmanguinhos/Fiocruz presented pre-grant patent oppositions against Gilead's applications for the base compound and the pro-drug.³²

However, during the pendency time Gilead enjoys a *de facto* monopoly over the sales of the medicine, which started in 2015. The last purchase was made at a price of USD 50 per pill, which amounts to around USD 4,200 for each standard treatment of 12-weeks.³³ Demand for sofosbuvir alone constitutes about USD 180 million of the Brazilian health budget per year.³⁴

There are generic versions of sofosbuvir available in the international market. Gilead signed voluntary licenses with generic producers in other countries limiting the geographical scope of countries that can have access to the generic versions produced under the licenses, which excludes Brazil. However, there are generic versions that have been produced outside of the Gilead licenses and that could be exported to Brazil at a fraction of the price charged by Gilead, around USD 185 for the same 12-week treatment.³⁵ **The savings with the purchase of the generic version could be around USD 170 million per year.**

Meanwhile, a public-private consortium led by the Oswaldo Cruz Foundation (Fiocruz) was set up to locally produce a generic version of sofosbuvir,³⁶ which is under development even before a decision about the patentability of the medicine by the patent office. Sofosbuvir was also included in the list of medicines that could be bought under the above-mentioned Mercosur joint purchase mechanism. However, due to an in-existent monopoly based only on pending patent applications, it is still being bought from Gilead with exclusivity, leading to an overspending of public resources.

3.4. Glatiramer – no granted patents, but no generic competition

Glatiramer acetate is used for the treatment of multiple sclerosis and is currently sold by Teva Pharmaceuticals under the brand name copaxone®. It was first registered in Brazil in 2006 and until now, Teva is the only producer with registration in the country. The medicine has been bought by the public health system under exclusivity from Teva since 2010. The price paid in the last public purchase in 2016 was USD 17 per each unit (20mg/ml), a total amount of USD 20.7 million.³⁷

With a preliminary search, we could identify 5 patent applications related to glatiramer in Brazil, **none of which have been granted**: 2 presented by Yeda Research and Development Co., 2 by Teva Pharmaceuticals and 1 by Dr. Reddy's Laboratories. It is worth noting that Teva bought the rights over glatiramer from Yeda in 1987.³⁸ The oldest patent application in Brazil was presented by Yeda in 1995 and was rejected first in 2003 and again in 2005 after the administrative appeal filed by the applicant. In 2009, Yeda challenged the rejection in a court case, which had a final decision in 2016 annulling the rejection of the patent application by the patent office due to administrative procedures. That patent application is now pending a new decision by INPI. 3 of the other 4 applications are still pending decision by the patent office and 1 was abandoned before any substantive analysis. Therefore, despite the legal uncertainty generated by the company's patenting strategies, there has never been a patent granted in Brazil for glatiramer. Nevertheless, the medicine is being bought under exclusivity from Teva since it entered in the Brazilian market in 2010.

In 2012, two Brazilian producers – one public and one private – announced a Partnership of Productive Development (PDP, for the acronym in Portuguese) to produce glatiramer in the country. There is no public information available about the current stage of development. However, in end 2016 the Brazilian Ministry of Health presented a request for the priority examination of the patent applications related to glatiramer, in which the PDP is mentioned as the justification for such a request.³⁹ Therefore, it is possible that the pending patent applications might be interfering with the local production of the medicine.

There is no generic version of glatiramer available yet in Brazil, but by law all generics are required to be at least 35% cheaper than the branded version. If this discounted price was applied to the last public purchase of the medicine, **there could have been savings of more than USD 7.2 million.**

4.

Final Remarks

4. Final Remarks

Access to medicines and health technologies is a complex and multifaceted issue. There are many factors that can interfere with the availability of treatment to those who need them. Price is one of these factors. And in the absence of competition, prices are usually higher. Patents are one way of preventing competition and creating a monopoly, and it has been extensively shown that patented medicines are much more expensive than generic medicines. Especially in cases of products where individuals don't have a choice (inelastic demand), it is possible for the producer to set the price as high as one can speculate that people are willing to pay. When it comes to health technologies, it can become literally a question of life or death, and people are willing to pay a lot.

For many years, we have been debating the impact of pharmaceutical patents on access to medicines, especially in developing countries. Most of the debate around the subject has been around HIV/AIDS treatment, and more recently Hepatitis C and some cancer drugs. Even though it has always been said that the patent system applies to all medicines and its implications cannot be limited to specific diseases areas.

Brazil has been appointed as one of the countries with the lowest number of granted patents for pharmaceuticals, which can lead to the impression that most medicines could be procured under competition in the country, resulting in lower prices. However, in the past years there has been a significant increase in public spending on medicines. To illustrate, a study⁴⁰ shows that while the spending by Ministry of Health on medicines increased by 74% from 2008 to 2015 (from BRL 8.5 billion to BRL 14.8 billion), the federal health budget only increased by 36.6% in the same period. While increasing public spending on medicines may reflect an increase in the number of individuals being treated, on the other hand it can also mean an increase in spending on high-price drugs, many of which are under monopolistic situations caused by the patent system.

With this study we aim to present new evidence on the issue of access to medicines in Brazil by looking at high-cost medicines purchased by the Brazilian MoH in 2016 and identifying those that only had one supplier at the Brazilian

market. After the initial selection, we will investigate the reasons behind that monopoly from the supply side. In order to do that, we will develop the patent status of each of those medicines in Brazil to verify if the monopoly is being caused by a granted patent or by pending patent applications, as well as analyse each patent/application to assess if it is primary or secondary and its potential to block competition. We will also compare Brazilian prices with generic prices in the international market to highlight the financial impact on the purchase of medicines by the public health system.

With the results, we intend to bring a better understanding regarding the purchases of medicines by the Brazilian public health system and the implications of the patent system, even in the absence of granted patents in the country. We intend, as well, to explore solutions that can be applied by public officials, especially when procuring the medicines, in order to minimise the impact of the patent paradox in Brazil. Final results are expected to be released mid-2018.

End Notes:

¹Among others: i) WHO. Research and Development to Meet Health Needs in Developing Countries: Strengthening Global Financing and Coordination. Report of the Consultative Expert Working Group on Research and Development: Financing and Coordination (CEWG), 2012. ii) Report of the United Nations Secretary-General's High-Level Panel on Access to Medicines: Promoting Innovation and Access to Health Technologies, 2016. iii) Vieira, MCF. Promoção do acesso e inovação em saúde: alternativas ao modelo baseado na proteção à propriedade intelectual em discussão na Organização Mundial de Saúde. Dissertação de Mestrado - Faculdade de Saúde Pública, Universidade de São Paulo, 2015.

²Among others: i) WHO. Report of the Commission on Intellectual Property, Innovation and Public Health (CIPHI), 2006. ii) WTO, WIPO, WHO. Promoting access to medical technologies and innovation: intersections between public health, intellectual property and trade, 2012.

³Among others: i) MSF, Untangling the Web of Antiretroviral Price Reductions, 11th edition, July 2008. ii) Correa, C. Guidelines for the examination of pharmaceutical patents: developing a public health perspective. WHO, ICTSD, 2007. In the Brazilian context: Vieira, F. S.; Zucchi, P. Diferenças de preços entre medicamentos genéricos e de referência no Brasil. Revista de Saúde Pública, v. 40, n. 3, 2006.

⁴It is important to mention, however, that when changing its national patent law to become TRIPS-compliant in 1996 Brazil adopted a TRIPS-plus mechanism of retroactive revalidation of patents granted abroad known as 'pipeline mechanism'. About 1,200 patents applications were filed through this mechanism (from May 1996 to May 1997). Those patents applications did not receive an examination of merit by the Brazilian patent system and are generally not considered in the comparative studies about patenting in the pharmaceutical sector. A non-exhaustive study identified 340 medicines that were protected by patents granted through the pipeline mechanism. For more information about the pipeline mechanism in Brazil, refer to: Hasenclever et. al., O instituto de patentes pipeline e o acesso a medicamentos: aspectos econômicos e jurídicos deletérios à economia da saúde. Revista de Direito Sanitário v.11 n2, Jul/Out 2010.

⁵Among others: i) Correa, C. Pharmaceutical Innovation, Incremental Patenting and Compulsory Licensing. South Centre, 2013. ii) Sampat, B.; Shadlen, K. Secondary Pharmaceutical Patenting: A Global Perspective. Research Policy, Volume 46, Issue 3, April 2017, Pages 693-707.

⁶Correa, C. 2013. Op. cit., p.10.

⁷Sampat, B.; Shadlen, K. Op. cit., p. 700.

⁸WIPO, World Intellectual Property Indicators 2017, 2017. Available at: http://www.wipo.int/edocs/pubdocs/en/wipo_pub_941_2017.pdf.

⁹This situation has been noted in studies related to the field. See, among others:
i) UK Government Intellectual Property Office. Patent Thickets. November 2011.

¹⁰For example, in the US, under the American Inventors Protection Act of 1999, 35 USC, par. 154(d), there is a right to obtain a “reasonable royalty” during pendency time.

¹¹Chaves, G.; REIS, R. Health, Intellectual Property and Innovation Policy: a case study of Brazil. In: Pharmaceutical Innovation, Incremental Patenting and Compulsory Licensing. South Centre, 2013.

¹²Kapczynski, A.; Park, C.; Sampat, B. Polymorphs and Prodrugs and Salts (Oh My!): An Empirical Analysis of “Secondary” Pharmaceutical Patents. PLoS ONE, v. 7, n. 12, e49470, p.1, 5 dez. 2012.

¹³Correa, C. Pharmaceutical innovation, incremental patenting and compulsory licensing. South Centre. Research Paper 41. September 2011.

¹⁴Among others: European Commission Competition DG. Pharmaceutical Sector Inquiry Final Report, 2009. In the Brazilian context: Pereira, D. G.; Fiuza, E. P. S. Os Direitos de Propriedade Intelectual nas Estratégias de Ciclo de Vida para Medicamentos de Segunda Geração: resultados parciais do inquérito brasileiro sobre a concorrência do setor farmacêutico. Radar - Tecnologia, Produção e Comércio Exterior, v. 1, p. 27–37, 2013.

¹⁵Reis, R. Panorama patentário dos medicamentos antirretrovirais no Brasil. Tese de Doutorado. Universidade Federal do Rio de Janeiro. 2012. The author makes a distinction between ‘incremental’ and ‘trivial’ innovation. The first means additional innovation to the first one and the last means only the attempt to protect market and to extend monopoly, without any additional innovation. This is an interesting approach to analyse secondary patents, nevertheless in our view, some incremental innovation fulfilling patentability requirements are still the exception and not the rule, especially if the country adopts restrictive interpretation of patentability requirements.

¹⁶Chaves, G. Interfaces entre produção local e acesso a medicamentos no contexto do Acordo TRIPS da Organização Mundial do Comércio. (Tese de Doutorado) Rio de Janeiro: ENSP/Fiocruz, 2016.

¹⁷Villard, P.; Scopel, C. A luta pelo tenofovir: vitórias e desafios futuros. In Políticas de produção local de medicamentos no Brasil: elementos para o debate. ABIA, 2017.

¹⁸Ação judicial n. 122-81.2010.4.01.3400, 21ª Vara Federal da Seção Judiciária do Distrito Federal. The lawsuit was presented by Gilead in 2010 and in 2015 Gilead presented a petition dropping the case after a judicial expert presented his opinion against the patentability of TDF.

¹⁹Villardj, Scopel, 2017, op. cit.

²⁰Information available at INPI website: www.inpi.gov.br, related to patent application number PI0406760-6. Last accessed on December 11, 2017.

²¹Brasil, Governo Federal. Páginas de Transparência Pública. Páginas da Transparência do Órgão Ministério da Saúde. Departamento de Logística em Saúde. Licitação n. 35/2017. Unit price R\$ 2,39. Conversion rate: R\$ 3,20. Last accessed on December 11, 2017.

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About the project:

accessibsa: Innovation & Access to Medicines in India, Brazil & South Africa

accessibsa is a tri-continental project enabled by a fellowship from the Shuttleworth Foundation. Our work expands access to life-saving medicines for those most in need. We make arguments for intellectual property systems that support public health – with safeguards for both sovereign human rights and genuine pharmaceutical innovation. For more, please see accessibsa.org

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The Patent Paradox in Brazil

IMPLICATIONS FOR PURCHASES OF
MEDICINES BY THE PUBLIC HEALTH SYSTEM

Marcela Fogaça Vieira and Gabriela Costa Chaves