EU-Mercosur Free Trade Agreement:

AN IMPACT ASSESSMENT STUDY OF TRIPS-PLUS PROVISIONS ON PUBLIC PROCUREMENT OF MEDICINES IN BRAZIL

Gabriela Costa Chaves,
Walter Gaspar Britto and
Marcela Fogaça Vieira

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Authors: Gabriela Costa Chaves, Walter Gaspar Britto and Marcela Fogaça Vieira

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1. Introduction

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The TRIPS[a] Agreement of the World Trade Organization (WTO), which came into effect on 1 January 1995, changed the international system of intellectual property with the establishment of minimum protection standards. This Agreement significantly changed the levels of protection practiced in developing countries, raising them, in most cases, to levels incompatible with their own stages of development.[1]

Resulting from an intensely private agenda, coordinated by a group of multinational companies,[b] and led by developed nations such as the United States, Japan and some European countries,[2] the TRIPS Agreement established the obligation to recognise intellectual property in all technological fields and by all member states of the World Trade Organization. The Agreement does however factor in varying implementation deadlines, according to the development classification of the member countries.

The negotiations of the Agreement did not occur without resistance from developing countries, which sought to minimise the negative impact by adopting provisions that would balance intellectual property rights abuses.[3] But for those who advocate the strengthening of global standards of intellectual property protection, the TRIPS Agreement fulfilled 95% of their expectations.[1]

The TRIPS Agreement was regarded as setting out the minimum standards for intellectual property protection, opening a window of opportunity to even higher standards – the missing 5% - to be negotiated outside the WTO multilateral forum and in a context of increased asymmetry among countries involved. The so-called 'TRIPS plus provisions' are those that go beyond the TRIPS Agreement, as a rule, strengthening the power conferred by intellectual property, and restricting the space for the adoption of measures that minimise the effects arising from the abuse of monopoly powers awarded by intellectual property.

For the pharmaceutical sector, with an emphasis on multinational pharmaceutical companies, the protection of intellectual property is a key instrument of its commercial and innovation strategies, particularly of industrial property which includes trademarks and patents. Patents guarantee companies a period of exclusivity in the market for their products, excluding the participation of third parties, without their consent, in the different stages involving production and trade. This allows them the power to set prices that, according to them, make it possible to recover their supposed R&D costs. Branding contributes to product differentiation market strategies, which together with other strategies aimed at influencing prescription patterns, contribute to increased sales for these products.[4]

In 1996, World Health Organization (WHO) member states adopted the World Health Assembly Resolution 49.14 (Resolution WHA 49.14 - Revised Drug Strategy Resolution)[5] calling for an analysis of the impact of WTO activities on national medicines policy and access to essential medicines, clearly indicating the concerns of developing countries about the effects of international trade decisions on health policies, especially towards medicines, in the context of global health.

These concerns, first expressed in 1996, have rapidly become magnified with the advent of highly active antiretroviral therapy for HIV infection, involving at least three antiretroviral drugs (ARVs) of different therapeutic classes.[6] This therapy has opened the prospect for changing the face of the HIV/AIDS pandemic that plagued the world since the 1980s with the possibility of saving lives and ensuring a better quality of life for people living with HIV. Many of these patented drugs have been traded (and still are) at inaccessible prices and have compromised (and still compromise) the ability of countries to offer treatment to their population.

More recently, cases such as that of the new medication Sofosbuvir, a drug that can cure chronic hepatitis C (above 90% efficacy rate) - initially marketed at USD 1,000 per tablet - as well as oncological drugs marketed at exorbitant prices, inaccessible even to the health systems of the wealthiest countries, rekindled the debate around the limits of intellectual property protection in the face of lack of access to medicines that have the potential to save millions of lives.[7-10]

The TRIPS Agreement has made it possible to safeguard public health through the so-called 'TRIPS flexibilities of public health protection', which allow for the removal of the exclusivity conferred by intellectual property right. This ensures the entry of generic drugs, enabling competition to encourage price reductions.[11-12] In 2001, the "Doha declaration on the TRIPS agreement and public health", adopted in the WTO framework, reaffirmed the right of countries to adopt such measures of public health protection.

2. Patents and the Challenges of Public Pharmaceutical Assistance Policy in Brazil

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In relation to industrial property, Brazil passed law number 9.279/96 to comply with the TRIPS Agreement, granting patent protection in advance for pharmaceutical processes and products as of May 1997. In addition, the law incorporated a series of TRIPS plus provisions which turned out to be harmful to access policies under the Unified Health System (SUS). Among the provisions incorporated in the Brazilian legislation are the mechanism of patent revalidation known as "pipeline" (articles 230 and 231), and the sole paragraph of article 40. It is worth noting the fact that the country did not use the transition period allowed under the TRIPS Agreement for the granting of pharmaceutical patents only from 2005. Both provisions had their validity questioned under the Brazilian constitution in the Federal Supreme Court (Direct Action of Unconstitutionality – ADI 4234 and ADI 5061 and 5529, respectively).

In the last twenty years, the assurance of pharmaceutical assistance in SUS has represented an important step forward in terms of expanding access to medicines for the Brazilian population,[13] and has also been the target of increasing challenges for the sustainability of policies on access to medicines. These include the growing incorporation of new technologies under monopoly[14] and the growing expenditure on medicines by the federal, state and municipal levels of government.[15-16] The expenses on medicines for the Ministry of Health (the federal entity being responsible for the purchase of the most high-cost technologies) went from 8.5 billion reais (BRL) in 2008 to 14.8 billion reais (BRL) in 2015.[17]

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-cost drugs, many of which are under monopolistic situations because they are subject to patent protection (pending patent applications or granted patents). According to the Institute of Socioeconomic Studies – INESC report,[17] there was significant growth in spending on specialised and strategic components of pharmaceutical assistance between 2008 and 2015, which are the ones that concentrate the largest number of medicines under monopoly situations. In ARVs, for example, there was a 12.5% increase in the

number of people treated between 2014 and 2015, but also a 30% increase in expenditures on drugs in the same period.[c]

Between 2001 and 2005 the growth in the Ministry of Health's expenditures on ARVs reflected a larger volume of purchased units, but also exemplified the budgetary weight of those medicines subject to patent protection. If from 2001 to 2003 expenditure on these drugs accounted for 60% to 70% of total ARV expenses, from 2004 to 2005 it reached 80%. In 2001, the share of generic drugs in ARV expenses was 42% and dropped to 20% in 2005. In 2005, of the 18 drugs offered by the Ministry of Health, 11 were under monopolistic patent protection.[18] In 2015 of the 22 drugs and fixed-dose combinations of ARVs provided by SUS, 11 were provided exclusively by multinational companies, accounting for 47.75% of total ARV expenditure in that year. However, these 11 drugs were only provided to 15% of the total number of people who were receiving ARVs treatment.

Furthermore, it is also possible to illustrate the losses to SUS caused by TRIPS plus measures applied to the pharmaceutical field, as shown in the examples below.

The patent revalidation mechanism (known as pipeline mechanism in Brazil) allowed the filing of patent applications in the pharmaceutical and food industries between May 1996 and May 1997, ensuring patent protection based on: i) the formal review of the application; ii) the non-exploitation of the invention in the country and iii) the granting of patent in the country of origin; thus by-passing the analysis of patentability criteria of novelty, inventive activity and industrial application at national level.[19] The second legal provision mentioned above (sole paragraph of article 40) allows for the extension of the patent term beyond 20 years in case the National Institute of Industrial Property (INPI) takes more than 10 years to grant the patent.

In the case of patents which were revalidated under the pipeline mechanism, Hasenclever et al[19] estimated the extra amounts that the Ministry of Health paid, compared to the purchase of generic versions for six[d] ARV (active principles) available in the international market, in different formulations, but which were protected by pipeline patents. Looking at the purchased volume and the difference between prices paid and prices available from two different sources (the World Health Organization – WHO and Médecins Sans Frontières - MSF) in the 2001 – 2007 period, *the loss was estimated at approximately USD 420 million (MSF minimum prices) and USD 519 million (WHO minimum prices).* Another study[20] estimated that from May 2009 to December 2010, the Ministry of Health spent *an extra BRL123 million* on the purchase of four drugs protected by pipeline patents (imatinib, lopinavir/ritonavir, olanzapine and atorvastatin) when compared to what it would have spent on generic versions of these products.

Article 40 of the Brazilian patent law has a sole paragraph which allows extension of patent term. A study[21] identified nine drugs purchased by the Ministry of Health,[e] whose patent applications are pending analysis by INPI for more than 10 years and, if granted, will have patent protection for over 20 years. Based on the years of accumulated extensions up to January 2016 and the average volume of purchases of the last 3 years, the authors estimated how much more

the government will pay for these nine drugs when compared to the possibility of buying generic versions and more affordable biosimilar drugs. The estimated amount was BRL 2.14 billion.

These are some examples that illustrate the damage caused to SUS by the adoption of TRIPS plus provisions in Brazilian legislation, which are enough to support the understanding that these measures should not be adopted in any case in intellectual property chapters proposed in trade agreements involving Brazil.

At the international level, different organisations recommend caution with the adoption of TRIPS plus provisions, as they may have a negative impact on the ability of the State to provide essential medicines, a component of the obligation of the state for the realisation of the human right to health. Recently, in September 2016, a report was published by the United Nations Secretary-General's High-Level Panel on Access to Medicines which had among its recommendations, an advisory to countries to conduct preliminary public health impact studies[22] while negotiating trade agreements.

The present study aims to contribute to the analysis of the impact that the trade agreement under negotiation between the EU and Mercosur can have on public health in Brazil, especially in public purchases of medicines.

3. Objectives

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General objective

Analyse the potential effect of TRIPS plus provisions on public procurement of medicines in Brazil present in the chapter on intellectual property of the European Union proposal in the framework of the negotiations of the Free Trade Agreement with Mercosur.

Specific objectives

- Map TRIPS plus provisions affecting access to medicines policies in the European Union proposal for the intellectual property chapter in the framework of the negotiations of the Free Trade Agreement with Mercosur
- Estimate the potential loss in Brazil government purchases brought about by the patent term extension for selected drugs.

4. Methodology

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The first stage of the research consisted of an analysis of the chapter on intellectual property that the European Union (EU) made available in September 2016 for the negotiation round with Mercosur. The chapter contains 26 articles[f] and is divided into three sections: 1) general provisions; 2) rules on intellectual property rights and 3) enforcement of intellectual property rights.

The analysis considered TRIPS plus provisions already widely discussed in literature[22–24] which affect policies on access to medicines negatively, either by strengthening intellectual property protection standards and the monopoly of pharmaceutical companies, or by stifling the possibility of using TRIPS safeguards for public health protection through the promotion of competition.

Once TRIPS plus provisions were identified, the second stage of the research consisted of case studies on the potential effects of one of these provisions on public procurement of medicines by the Ministry of Health, such as the extension of the patent term beyond 20 years (the period necessary for obtaining market authorisation in the country).

To estimate the extension period of the patent term of the list of selected medicines, we considered the date of the oldest patent application (A) of each product that had a decision pending or that had been granted in Brazil. The information on the dates of market approval dates (B) for these products in Brazil were identified through the website of the Brazilian National Agency of Sanitary Surveillance [Brazilian Health Regulatory Agency] (Anvisa[g]). The difference between the filing date of the patent application in Brazil and the date of the market approval in the country with the subtraction of five years (as foreseen in the proposal submitted by the EU), was considered as the patent term extension period for the product (Y=(B-A)-5).

In our sample, we included antiretrovirals (ARVs) for the treatment of HIV/Aids, direct-acting antivirals for the treatment of hepatitis C virus infection prescribed in 2015 and cancer drugs and inhibitors of tyrosine kinase. We identified the following products which would have their patent protection extended by the

application of the above-mentioned TRIPS plus provision (if it was enforceable in 2015): darunavir (0.1 year), etravirine (4.4 years), raltegravir (0.3 year), sofosbuvir (5.9 years), daclatasvir (2.4 years), dasatinib (1.9 years).

Subsequently we collected prices per unit and quantities (volume) purchased of these medicines by the Ministry of Health for the year 2015, and the prices of generic versions available on the international market.[h] We estimated contracted expenditure in the year by multiplying the price by volume (C). We also estimated how much would have been spent had the Ministry of Health procured the generic version of these drugs (D), multiplying the generic price by the volume purchased. The difference (C – D) refers to the extra amount paid due to monopoly market conditions. The patent term extension cost (D) to SUS was estimated by multiplying the difference between the expenses involving the price paid by Brazil and the generic price and the patent term estimated extension period [E = (CD) Y].

5. Results and Discussion

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5.1. Mercosur – EU Free Trade Agreement.

A brief history of the negotiations

Negotiations on a trade agreement between the European Union (EU) and Mercosur began in the year 2000. Intensive negotiations were held in 2004 with the objective of concluding the agreement by the end of that year. However, in October 2004, at a ministerial meeting in Lisbon, Portugal, both parties agreed that they would need more time to draft the agreement and the negotiations were suspended. In May 2010, negotiations were officially resumed and since then, 26 rounds of negotiations have taken place (including the Bi-regional Negotiating Committee Meeting - BNC). The last round took place in October 2016 in Brussels, Belgium,[i] and the next one is scheduled to take place in Buenos Aires, Argentina, from 20 to 24 March 2017.

The aim is to negotiate a comprehensive trade agreement covering not only trade in industrial and agricultural goods but also services and public procurement as well as intellectual property and other technical barriers to trade. Unlike most trade agreement negotiations, the EU made the text proposed for three chapters of the agreement being negotiated, public. They are: (i) intellectual property rights,[j] (ii) small and medium-sized companies,[k] and (iii) public companies.[l] The chapter on intellectual property also contains a section relating to online trading, which is not discussed here.

Analysis of the text of the EU proposal for the chapter on intellectual property

We analysed the text of the proposal presented by the EU for the chapter on intellectual property and identified three TRIPS plus provisions that are highlighted in the literature as likely to affect the adoption of access to medicine policies negatively. These are: (i) restriction of parallel import, (ii) data exclusivity, and (iii) extension of patent term.

i) Exhaustion of intellectual property rights

Article 3 of the EU proposal addresses the exhaustion of intellectual property rights. Under the proposal, the parties would either adopt the national regime, or the regional exhaustion regime. Under WTO TRIPS Agreement countries may choose the exhaustion regime they consider most appropriate (Articles 6 and 28 of the TRIPS Agreement and Article 5d of the Doha Declaration on TRIPS and Public Health). Thus, by means of TRIPS, countries may also opt for the international exhaustion regime, which would not be possible if the EU proposal was accepted.

The exhaustion of intellectual property rights refers directly to the issue of parallel imports, one of the safeguards provided for in the TRIPS legal framework. According to the definition adopted by the WTO, parallel import is "when a product made legally (i.e. not pirated) abroad is imported without the permission of the intellectual property right-holder (e.g. the trademark or patent owner). Some countries allow this, others do not".[m]

From the point of view of public health policies, parallel imports are an important measure as it allows the importation of products that are legally available for sale in other markets, often at lower prices than those practiced in the importing country.

It is worth remembering the emblematic case of (the government of) South Africa, which in 1998 was sued by multinational pharmaceutical companies for having changed its patent law to include, among other things, parallel importation. During the three-year period in which the law was suspended, 400,000 people died in South Africa from HIV/AIDS, almost all without having access to life-saving drugs which were sold at inaccessible prices by patent rights holders.[n]

Brazilian legislation dealing with industrial property currently adopts the national regime of exhaustion of rights (Article 43, Industrial Property Law - LPI). However, there are two bills under discussion in the Brazilian house of representatives (*Câmara dos Deputados*) that proposes to exchange the Brazilian regime for the international exhaustion regime: Bill [PL] 139/99 (authored by Alberto Goldman - PSDB/SP) and Bill 8091/2014 (authored by the Social Security and Family Commission)[o]. In case the EU proposal is accepted, it will no longer be possible to change the exhaustion regime as proposed in the bills that still are under debate in the National Congress.

ii) Extension of the period of protection conferred by a patent on medicinal products

According to Article 8.3 of the proposal submitted by the European Union, countries should extend the term of validity of a patent for a medicinal product that has undergone an administrative authorisation procedure for its commercialisation. The extension period is the period between the filing of the patent application and the first authorisation to place the product on the national market, reduced by 5 years. In the case of medicinal products for which studies for paediatric formulations have been carried out, countries should grant a

further extension of the patent term for a period not specified in the proposal text. The same provision applies to patents on phytopharmaceutical products [plant production products] (Article 8.5).

In the TRIPS framework, the validity of the patent will not end before the expiration of a twenty-year period starting from the date of filing (article 33). There is no provision dealing with the extension of patent periods, either based on the time required to obtain a marketing authorisation such as that proposed by the EU in the FTA with Mercosur, or on the time spent by patent offices to analyse patent applications, as proposed in other FTAs.

The extension of a patent term increases the length of time a drug or a health care product is under monopoly, with the already highlighted adverse consequences on access.

Brazilian law already adopts a patent extension mechanism in cases where the patent application takes more than 10 years to be analysed. Article 40, the sole paragraph of the patent law, states that the term of validity of the patent shall not be less than 10 years from the grant date. This legal provision had its constitutionality recently challenged in the Federal Supreme Court (STF) by the Direct Court Action of Unconstitutionality (ADI) 5061, filed by ABIFINA - Brazilian Chemical Industry, Biotechnology and Specialties Association in November 2013, and by ADI 5529, filed in May 2016 by the Attorney General of the Republic (PGR). In addition, two bills under discussion in the house of representatives aim to exclude the sole paragraph of Article 40 of the patent law, Bill 3944/12, authored by Jandira Feghali - PCdoB/RJ; José Linhares - PP/CE; Dr. Paulo César - PSD/RJ and others and Bill 5402/13, authored by Newton Lima - PT/SP and Dr. Rosinha - PT/PR.

iii) Protection of data submitted to obtain an authorisation to put a medicinal product on the market

In accordance with Article 10.2 of the EU proposal, the parties shall not allow any other manufacturer of the same or similar product to obtain marketing approval based on a marketing approval granted to the manufacturer who provided the results of pre-clinical or clinical tests, for a period of […] years (the number of years is not specified in the proposal). An additional period, also not specified in the proposal, would be granted in case of authorisation to one or more new therapeutic indications that may be considered of significant clinical benefit. In other FTAs signed with the EU, a minimum period of 5 years was adopted.

Under the TRIPS Agreement, member countries must protect undisclosed test data against unfair commercial use (Article 39.3), but no exclusive rights to data are required.

Granting test data exclusivity for clinical and preclinical trials can be very detrimental to public policies of access to medicines as it may delay the availability of generic versions of the drugs on the market for many years. Or, it can force generic producers to conduct new clinical trials at the expense of ethical principles in human research (the Helsinki Declaration of the World Medical Association), and raising the costs of producing generics.

There are a number of studies that estimate the impact of TRIPS plus provisions, including data exclusivity, on drug spending in the public and private sectors, as well as domestic production in Latin American countries.[25–29] For example, in Ecuador the adoption of data exclusivity in 2008 could result in an increase of USD 24.47 million in public spending on drugs by 2020. In Peru, the adoption of data exclusivity for 10 years in 2009 may result in an increase in drug spending (public and private) of more than USD 300 million by 2025.

In Brazilian legislation, the data needed to obtain marketing approval of pharmaceutical products for veterinary use, fertilisers and agrochemicals is entitled to data exclusivity for a period of 10 years (Law 10603/02). This law does not apply to pharmaceuticals for human use, not by omission but by deliberate choice of the legislator. The Industrial Property Law (LPI) protects undisclosed data against unfair commercial use (Article 195, XIV), in compliance with the TRIPS Agreement.

Nonetheless, it is relevant to mention that there are ongoing lawsuits in different levels of jurisdiction in which major drug companies demand exclusivity over data presented to obtain marketing approval of drugs for human use. A study by Pro-Generics estimated that the withdrawal of the generic drug escitalopram (anxiolytic) for two weeks from the market left 50,000 people without access to the drug as a result of a lawsuit filed by Lundbeck Laboratories requesting data exclusivity.[30]

Currently there is a bill (PL 5.402/13) in the house of representatives that aims to amend article 195 of the patent law to avoid any interpretation of the law that could lead to the granting of data exclusivity to pharmaceuticals for human use.

6. The Effect of TRIPS-plus Provisions on Public Procurement of Medicines in Brazil

6. The Effect of TRIPS- plus Provisions on Public Procurement of Medicines in Brazil

As discussed in the previous section, one of the TRIPS plus provisions proposed by the European Union is to extend the term of drug patents because of the time required to obtain marketing approval in Brazil.

Table 1 below provides estimates of extended patent protection terms for selected drugs, assuming EU proposed TRIPS plus provisions had been in force in Brazil in 2015. Table 2 presents estimates on the additional expenditure the Ministry of Health would incur in case the TRIPS plus provision for the extension of patent terms were to be applied. **The total amount would be USD 444,081,767.74 or roughly BRL 1.22 billion for just 6 drugs.**

To put this into perspective, the estimated amount of the additional expenditure with only six medicines represents 8.24% of the Ministry of Health's total expenditure on drugs in 2015.[17,p] An analysis by pharmaceutical assistance financing components show that the extra amount related only to the three ARVs (darunavir, etravirine, raltegravir) is equivalent to 10.11% of the Ministry of Health's total expenditure on STD/AIDS drugs in 2015. The estimated additional cost for two direct-acting antivirals (DAAs) represents 16.8% of Ministry of Health expenditure with the Specialized Component of Pharmaceutical Care in 2015.

Another possible comparison that would put our data in perspective is an analysis in relation to Constitutional Amendment 95/2016 (formerly known as Proposal for Constitutional Emendation - PEC 241/55), which deals with public spending expenditure ceilings. A long-term estimate pointed to a reduction in health resources in the order of BRL 205 billion over the next 20 years, an average of BRL10.25 billion a year.[q] The estimated additional expenditure on procurement of six drugs that would have their patent protection extended by the EU FTA proposal would be BRL1.22 billion, which represents 11.9% of the estimated annual loss to the health budget following the imposition of Constitutional Amendment - EC 95/2016.

Table 1 - Estimate of the extended years of patent term for selected drugs

Drugs	Number of the patent application considered in the study (Date of deposit in Brazil)	Date of marketing approval in Brazil	Days between the filing of the patent in Brazil and the marketing approval (Conversion in years) (A)	Estimated patent term extension (E=A-5)
Darunavir	PI0208796-0 (09/04/2002)	21/05/2007	1,868 days (5.1 years)	0.1 years
Etravirine	PI9915552-4 (24/09/1999)	02/02/2009	3,419 days (9.4 years)	4.4 years
Raltegravir	PI0213522-1 (21/10/2002)	28/01/2008	1,925 days (5.3 years)	0.3 years
Sofosbuvir	PI0410846-9 (21/04/2004)	27/03/2015	3,992 days (10.9 years)	5.9 years
Daclatasvir	PI0716483 (07/08/2007)	06/01/2015	2,709 days (7.4 years)	2.4 years
Dasatinib	PI 0009721-7 (10/04/2000)	03/12/2007	2,525 days (6.9 years)	1.9 years

Source: Calculated by the authors based on information on the marketing approval obtained at Anvisa and information on patents from the INPI website.

Table 2 - Estimates of the additional expenditure due to patent term extension of selected drugs. Brazil, 2015

Drugs	Price paid by the Brazilian government in 2015 (unit price in USD*)	Lowest price of the generic version available on the international market in 2015 (unit price in USD*)	Volume purchased by the Brazilian government in 2015 (pharmaceutical units) (C)	Difference between contracted expenditure paid by Brazil and if it had been purchased at the lowest price(USD) D=(AxC)-(BxC)	Years of patent term extension due to marketing approval time (if adopted) (E)	Estimate of additional expenditure in case of patent term extension (USS) G= DxE
Darunavir (150mg)	0.87 (1)	0.39 (3)	154,800 (1)	74,304	0.1	7,472.62
Darunavir (600mg)	3.49 (1)	1.48 (4)	8,280,000 (1)	16,642,800	0,1	1,659,656.40
Etravirine (100mg)	2.16 (1)	0.30 (5)	3,120,000 (1)	5,803,200	4.4	25,584,000.00
Raltegravir (400mg)	4.98 (1)	0.83 (4)	7,920,000 (1)	32,868,000	0.3	9,852,490.85
Sofosbuvir (400mg)	29.76 (2)	8.93 (6)	2,684,304 (2)	55,914,052	5.9	329,950,499.21
Daclatasvir (60mg)	11.04 (2)	2.18 (6)	1,834,056 (2)	16,249,736	2.4	38,999,366.78
Dasatinib (100mg)	34.20 (7)	4.66 (8)	618,540 (7)	18,271,672	1.9	34,716,176.04
Dasatinib (20mg)	6.84 (7)	0.93 (8)	294,960 (7)	1,743,214	1.9	3,312,105.84
Total	-	-	-	-	-	**444,081,767.74**

*Exchange rate considered: USD 1.00 = BRL 2.75

Sources: 1) Ministry of Health, Department of HIV/AIDS and Viral Hepatitis (DDAHV/SVS/MS), 2016. Obtained via Access to Information Law. 2) Ministry of Health, Department of Pharmaceutical Assistance, 2016. Obtained via Access to Information Law. 3) MSF, Decisions around HIV treatment in 2015: Seven ways to fail, derail or prevail, 2015. 4) WHO-GPRM. 5) MSF, Untangling the Web, 18th edition, 2016. 6) HepCAsia, Generic DAAs Pricing. Sofosbuvir, data from May 2015. Daclatasvir data from January 2016. 7) Brazil, Transparency Portal of the Federal Government - Ministry of Health. 8) Mims.com apud t'Hoen, Access to cancer treatment, 2014. The price of the generic version considered for the study was of 2013 and for the 50mg tablet (unit price of US$ 2.33). For the purposes of this study, we consider the price per milligram to calculate the generic price of the 20mg and 100mg tablets used in Brazil.

7. Final Considerations

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From our analysis, it is evident that the intellectual property chapter proposed by the European Union presents a set of TRIPS plus provisions that, if approved, will be harmful to public policies of access to medicine in Brazil. The estimated additional expenditure of USD 444,081,767.74 for only 6 drugs purchased by the Ministry of Health with the adoption of one of the proposed provisions is clear evidence of this harmful effect. Considering the search for coherence between public policies in different areas we recommend the non-adoption of TRIPS plus provisions by Mercosur in its Free Trade Agreement with the European Union.

We also recommend that the Brazilian government and other countries involved in the negotiation of the FTA carry out an impact study in the field of public health and human rights, as recommended recently by the UN High-Level Panel on Access to Medicines.

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End Notes:

[a]Agreement on Trade-Related Aspects of Intellectual Property Rights.

[b]During the negotiations of the TRIPS Agreement, in the Uruguay Round of GATT, the Intellectual Property Committee (IPC) advised the United States, in conjunction with other developed countries. The IPC was composed of the following companies: Bristol-Myers, CBS, Du Pont, General Electrics, General Motors, Hewlett-Packard, IBM, Johnson & Johnson, Merck, Monsanto, Pfizer (Sell, 2003).

[c]Data available at the access to information system of the Federal Government – E-SIC.

[d]The six ARVs analysed were: abacavir, amprenavir, efavirenz, lopinavir/ritonavir, nelfinavir and ritonavir.

[e]Adalimumab, erlotinib, maraviroc, raltegravir, cinacalcet, sofosbuvir, trastuzumab emtansine, gefitinib, etravirine.

[f]Section 1 - General provisions: Article 1 - Objectives; Article 2 - Nature and scope of obligations; Article 3 - Exhaustion. Section 2 - Standards relating to intellectual property rights: Article 4 - Copyright and related rights; Article 5 - Trademarks; Article 6 - Designs; Article 7 - Geographical indications; Article 8 - Patents; Article 9 - Cultivar; Article 10 - Protection of confidential information. Section 3 - Enforcement of Intellectual Property Rights: Subsection 3.1 - General Provisions (Article 11 - General Obligations and Article 12 - Persons entitled to request application of measures, procedures and remedies); Subsection 3.2 - Compliance in civil and administrative matters (Article 13 - Evidence Article 14 - Right to information Article 15 - Provisional and precautionary measures Article 16 - Medicines Article 17 - Judicial orders Article 18 - Alternative measures Article 19 - Article 24 - Legal proceedings - Article 21 - Publication of judicial decisions - Article 22 - Presumption of authorship or possession - Article 23 - Administrative procedures - Article 24 - Consistency with GATT and TRIPS Agreement Article 26 - Cooperation.

[g]Website address for health record inquiry - http://consultas.anvisa.gov.br/#/medicamentos/

[h]Data sources are listed in the part of presentation of the results below.

[i]An official report of the 26th round of negotiations is available at: http://trade.ec.europa.eu/doclib/docs/2016/november/tradoc_155069.pdf Last accessed on 10/01/2017.

[j]Available at: http://trade.ec.europa.eu/doclib/docs/2016/november/tradoc_155071.pdf Last accessed on 21/02/17.

[k]Available at: http://trade.ec.europa.eu/doclib/docs/2016/november/tradoc_155072.pdf Last accessed on 21/02/17.

[l]Available at: http://trade.ec.europa.eu/doclib/docs/2016/november/tradoc_155072.pdf Last accessed on 21/02/17.

[m]Available at: https://www.wto.org/english/thewto_e/glossary_e/glossary_e.htm Last accessed on 07/03/2017.

[n]MSF, Access Campaign. Drop the case! Support the struggle for medicines in South Africa. March, 2001. Available at: https://www.msfaccess.org/about-us/media-room/press-releases/drop-case-support-struggle-medicines-south-africa

[o]Bill 139/99 (authored by Alberto Goldman - PSDB / SP) proposes to exchange the national exhaustion regime for the international exhaustion of rights, allowing parallel importation in cases where the product has been placed on the market by the patent holder or with its consent. Bill 8091/2014 (authored by the Social Security and Family Commission) also proposes a change to the regime of international exhaustion of rights, but allows for the importation of any medicine legally placed in the market of another country, even when it does not have the patent holder's consent.

[p]The amounts presented for expenditure with procurement of drugs in 2015 were adjusted by the Extended National Consumer Price Index - IPCA of March 2016: BRL14.8 billion for total expenditure of the Ministry of Health with medicines; BRL1,008,877,660 for the Ministry of Health's expenses with STD/AIDS drugs; BRL 6,040,371,675 for the expenses of the Ministry of Health with the Specialised Component of Pharmaceutical Assistance (David et al., 2016).

[q]Vieira, FS; Benevides, RPS (2016). The impacts of the new fiscal regime for the financing of the Unified Health System and for the realization of the right to health in Brazil. IPEA, Technical Note No 28. Available at: http://www.ipea.gov.br/portal/images/stories/PDFs/nota_tecnica/160920_nt_28_disoc.pdf

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About the authors:

Gabriela Costa Chaves is graduated in Pharmacy (2002) and holds a Masters and PhD in Public Health from the Oswaldo Cruz Foundation (2005 and 2015). Since January 2013, she has been working as a researcher for the team of the Department of Pharmaceutical Policy and Pharmaceutical Services (NAF) of the Sergio Arouca National School of Public Health – ENSP/Fiocruz. Previously, she has worked with national and international organizations working on access to medicines issues in Brazil and Latin America, subject in which she has published extensively.

Marcela Fogaça Vieira is graduated in Law (2006), specialized in Intellectual Property Law and New Technologies of Information (2010) and holds a Master's degree in Health Policy and Management (2015). She has been working with access to medicines and intellectual property issues at civil society organizations in Brazil since 2005 and has provided consultancy for several international organizations. She has published several articles in this subject. Nowadays, she is a consultant for the Suttleworth Foundation, in the AccessIBSA Project.

Walter Britto Gaspar is a Graduate of the Getulio Vargas Foundation Law School (2015) and currently a Master's candidate in Public Health at the Rio de Janeiro State University (UERJ). He has been working with access to medicines and intellectual property issues since 2013 as a volunteer and as Coordinator of Universities Allied for Essential Medicines in Brazil. Currently, also a research assistant at ENSP/Fiocruz.

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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