



WHY BRAZIL SHOULD REFORM ITS PATENT LAW AND BOOST MEDICAL INNOVATION TO PROMOTE ACCESS TO MEDICINES

Governments have a responsibility to act to protect and improve the health of people.

Brazil is one of many governments working to strike a balance between public and private interests in determining how medical innovation is conducted and incentivised – and how medical products and technologies can be made accessible for the benefit of public health.

One key area where governments can intervene is ensuring medicines aren't priced out of reach. Multiple strategies can be adopted to reach this goal: one is determining with precision what type of pharmaceutical products deserve a patent, with the aim of eliminating the granting of unnecessary or frivolous patents that keep drug prices higher for longer; another is using the mechanisms that are authorised by international trade rules to overcome patent barriers, once patents have been granted. The most critical aspect is having a patent law that is well-designed and provides an adequate framework for public health goals to be met.

One other key area is that of medical innovation. The current paradigm for research and development (R&D) is one where medical innovation is incentivised through the promise of high drug prices, backed by patent monopolies. This model leaves many pressing health needs unaddressed. Governments need to intervene to address this market failure by boosting



their contribution to medical research and by ensuring drug development is done in a way that doesn't automatically lead to high prices.

The Brazilian Congress is already compiling evidence on the need for reform of the patent law and the need to explore alternative mechanisms to promote medical research that responds to priority health needs. In October 2013, after broad consultations with multiple stakeholders from Brazilian society, the Center of Studies and Strategic Debates (CEDES), a technical-consultative body comprised of 11 parliamentarians¹ published "Brazil's Patent Reform: innovation towards national competitiveness". One year later, in October 2014, the

Commission on Social Security and Family approved the Report from the "Special Sub-Commission on the Development of the Health Industrial Complex, Production of Drugs, Equipment and Other Inputs"². Both documents encourage changes in the patent law and with the medical innovation framework, based on concrete proposals.

At this point, several bills and recommendations have been tabled in the Brazilian Congress. Approval of these would both ensure the patent law is better suited to answer public health needs, and enable Brazil to play a leading global role in addressing the fundamental flaws in medical research. The time to act is now.

I - THE CONTEXT: INTERNATIONAL OBLIGATIONS, NATIONAL PREROGATIVES



In 1995, members of the World Trade Organization (WTO) adopted the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement, under which countries agreed to set minimum standards for patent protection, including on pharmaceutical products.

Brazil did not grant pharmaceutical patents at the time, but was obliged to introduce such measures upon inception of the WTO. Following intense pressure from the US government and multinational pharmaceutical companies, an Industrial Property Law was adopted in 1996, despite the availability of a 'transition period' which would have allowed Brazil to wait until 2005 to introduce patent laws.

The impact of this rapid implementation was felt strongly in public health programmes in Brazil. The universal access to HIV/AIDS treatment programme, which was initiated in 1996, had as one of its main pillars ensuring the accessibility of medicines by relying on affordable, locally produced generic drugs. Following the 1996 law, however, generic production was only possible for medicines introduced in Brazil prior to 1997. As newer, more effective but patented drugs started to be introduced into HIV treatment guidelines, the financial burden of the treatment programme increased exponentially, and the

sustainability of the Brazilian response to HIV was put at risk.

Committed to universal access to treatment, yet faced with an ever-increasing demand for patented and expensive drugs, Brazil prioritised efforts to reform the international intellectual property system. Brazil's push to change international norms so that they would ensure access to essential medicines culminated in the approval of the Doha Declaration on TRIPS and Public Health in 2001. 'Doha' was a landmark political moment, which confirmed that countries have the prerogative to use flexibilities in order to protect public health.

“The TRIPS Agreement, for all its provisions on the protection of scientific knowledge, contains measures allowing for the promotion of public health. We are pleased that this Special Session has acknowledged the efforts of countries to develop domestic industries in order to increase access to medicines and protect the health of their populations.”

JOSÉ SERRA, MINISTER OF HEALTH OF BRAZIL, SPECIAL SESSION OF THE GENERAL ASSEMBLY OF THE UNITED NATIONS ON HIV/AIDS, JUNE 2001

Brazilian civil society played a key role in securing the constitutional recognition that “healthcare is the right of all citizens and the duty of the State”, in pushing government to make AIDS treatment a high priority and introduce health-oriented IP reforms. GTPI, a coalition of NGOs created in 2003, advocates for the rights of people living with HIV (PLHIV) and pushes for the use of flexibilities allowed within the framework of international trade rules.



II - MECHANISMS TO ENSURE ACCESS TO MEDICINES: WHAT BRAZIL HAS ACCOMPLISHED

Brazil has already put in place a number of policies and taken steps to ensure access to medicines for its population.

❖ ANVISA's Prior Consent

In Brazil, officials from the Agência Nacional de Vigilância Sanitária (ANVISA, the body responsible for regulation and approval of medicines in the country) participate in the process of analysing patent applications on pharmaceutical products, instead of leaving this task exclusively to patent office examiners. This provision, known as 'prior consent,' was adopted in 2001 in order to "ensure the best technical standards in the process of decisions over pharmaceutical patents"³. It allows ANVISA to work in partnership with the National Institute of Industrial Property (INPI). ANVISA's prior consent is critical to ensure the patent law is implemented in a way that balances the private rights of patent applicants with the public interest.

- **National impact:** Of the 1,346 patent applications analysed by ANVISA between 2001 and 2009, 209 did not receive prior consent. 90 of these had been approved by INPI, but were subsequently rejected following ANVISA's review. ANVISA's prior review also contributed to the quality of patent applications: of the 988 applications that received ANVISA's prior consent, about 40% were required to reduce the scope of claims or to enhance disclosure of the invention.
- **International impact:** ANVISA's prior consent is seen as a model to be reproduced in other countries. The final Report of the World Health Organization's Commission on Intellectual Property Rights,

"We are determined to use all TRIPS flexibilities, including the issuing of compulsory licences, if this is the only way to guarantee the continuity of our HIV/AIDS programme."

**DR. HUMBERTO COSTA, MINISTER OF HEALTH OF BRAZIL,
WORLD HEALTH ASSEMBLY, MAY 2005**

Innovation and Public Health in 2006, for example, identifies the participation of public health authorities in the analysis of pharmaceutical patent applications as a positive measure that protects public health, since it helps to prevent granting of frivolous patents.

❖ Patent oppositions

Out of the huge number of patent applications made by pharmaceutical companies, only a few refer to genuine inventions, and most are for minor variants of already known pharmaceutical substances. Such 'low-quality' patents can be avoided if countries provide strict standards in their patent-granting process, but even then there is no guarantee that patent offices will enforce them.

Patent opposition procedures can apply pressure for more rigorous standards during the patent examination process, reinforcing the need to reject non-qualifying patents. They can also present new arguments which were not previously considered by the patent office, thus improving patent quality. Brazil's law adopted the model of "support to examination", which allows interested parties to present arguments and documents to the patent examiner.

- **National impact:** In 2006, when the first generic versions of tenofovir, a critical drug for the treatment of HIV, reached the international market, the price charged in Brazil by the company Gilead, who had filed a patent application, was 10 times higher than the most affordable generic option available. In order to encourage competition that would bring the price down, patent oppositions were filed by the Grupo de Trabalho em Propriedade Intelectual (GTPI), a civil society organisation, and by Farmanguinhos, Brazil's largest government-owned laboratory. In August 2008, INPI rejected the patent application for tenofovir on the grounds that it lacked inventiveness, as claimed in the patent oppositions. Thanks to the rejection, the government was able to explore options to supply the drug at lower prices.
- **International impact:** The patent opposition presented in Brazil helped show that Gilead's monopoly over tenofovir was sustained by a patent that could be successfully challenged. The opposition also helped to emphasise the importance of ensuring the patent law and patent examination process enables the rejection of patent applications when these are undeserved.

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Compulsory licences

A compulsory licence is a government order that allows a company other than the patent-holder to manufacture a patented product without the consent of the patent owner (although the patent owner is still paid for use of the patent), or to enable the import of such a product from a generic manufacturer in another country. Compulsory licensing has been incorporated into Brazilian legislation and can be issued for a number of reasons, including economic abuses by the patent owner, or in the case of a national emergency or a public interest declared by the federal authorities.

- **National impact:** In Brazil, the threat of issuing a compulsory licence has been used to pressure drug companies during price negotiations for medicines to treat HIV/AIDS. This strategy has saved the Brazilian

Health Ministry US\$1.2 billion in treatment costs in recent years.⁴ When a compulsory licence was issued for efavirenz in 2007, the price dropped from \$580 for one year's treatment to \$158. Over five years, the savings generated by the compulsory licence were approximately \$103 million and the number of patients treated with the drug increased around 30%⁵.

- **International impact:** The threats to issue compulsory licences were backed up by a strategy involving government-owned laboratories, which were able to calculate the cost of manufacturing specific drugs. Brazil thereby helped to increase transparency of global drug prices, and prompted a global policy dialogue on affordable access to treatment. In addition, a strong market demand for active

pharmaceutical ingredients, in order to be able to produce generics locally, created economies of scale and contributed to transforming the market for HIV medicines in to a low-margin, high-volume model.⁶ Other countries have also issued compulsory licences, including Thailand in 2006 and 2007, Ecuador in 2009 and 2012, Indonesia in 2012, and India in 2012.

“Between our trade and our health, we have chosen to look after our health.”

**LUIZ INACIO LULA DA SILVA,
PRESIDENT OF BRAZIL, SPEAKING
ON BRAZIL'S DECISION TO ISSUE
A COMPULSORY LICENCE ON THE
HIV DRUG EFAVIRENZ, 2007**

MEDICAL INNOVATION

Brazil has played an important role in the development of WHO's Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (GSPOA), which was a significant milestone in addressing issues of sustainable research and development, innovation and access to medicines. In seeking a meaningful implementation of GSPOA, Brazilian representatives have made several political statements in different multilateral fora recognising that: 1) intellectual property does not necessarily have a positive effect on economic development; 2) patents can have a dramatic

impact on access to medicines when they are used to prevent competition; and 3) there is insufficient R&D for diseases that prevail in developing countries. Increasingly, Brazil has been supporting the view that cooperation on health R&D must rely on mechanisms that promote open knowledge innovation, data sharing and coordinated R&D efforts.^{1,7}

“The granting of frivolous patents may do enormous harm to R&D activities and disrupt the necessary flows across innovation chains.”

**BRAZILIAN DELEGATION AT THE
TRIPS COUNCIL - WORLD TRADE
ORGANIZATION, 2012**



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III – NEXT STEPS: WHY BRAZIL SHOULD REVIVE ITS LEADERSHIP ON ACCESS TO MEDICINES AND MEDICAL INNOVATION

“Increasing access to new therapies and technologies is also important. Brazil respects its intellectual property commitments. Yet we are convinced that the flexibilities contained in the WTO’s TRIPS Agreement, in the Doha Declaration on the TRIPS Agreement and Public Health, and in the World Health Organization’s Global Strategy on Public Health, Innovation and Intellectual Property, are indispensable for policies that guarantee the right to health.”

DILMA ROUSSEFF, PRESIDENT OF BRAZIL, AT THE UN HIGH-LEVEL MEETING OF THE GENERAL ASSEMBLY ON THE PREVENTION AND CONTROL OF NON-COMMUNICABLE DISEASES, SEPTEMBER 2011

Despite these important initiatives to secure access to medicines, challenges and threats remain. Brazil, with one of the oldest cohorts of people on HIV treatment in the world, will face increasing pressure as more and more people develop resistance to their medicines and will need to be switched to second-line or third-line regimens – which typically cost double and at least 15 times more than a first-line combination, respectively.

The challenges caused by high prices are not limited to HIV; the prices announced for many new drugs, including bedaquiline for tuberculosis, sofosbuvir for hepatitis C and many cancer medicines, are astronomically high, particularly in middle-income countries such as Brazil which represent growing market opportunities for the pharmaceutical industry.

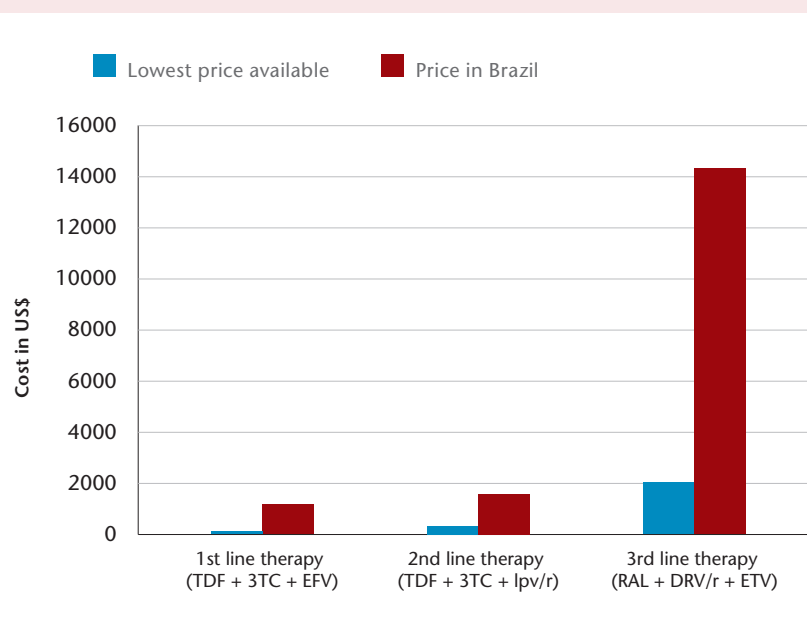


Access to medicines is intrinsically linked to the way we pay for medical research and drug development. The current R&D model not only leads to higher prices, as it gives patent-holders a free hand in determining prices without providing any transparency on the

real costs of drug development, but it also steers innovation away from areas of greatest health need and towards areas of greatest profitability, skewing priorities and leaving many pressing health needs unaddressed.

ANTIRETROVIRAL PRICES IN US\$, 2013

Source: Brazilian Ministry of Health, reply to access to information request 2013



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The report *Brazil's Patent Reform: Innovation Towards National Competitiveness* (2013) reinforces the point that using patents to reward innovation is a flawed model, leading to a growing innovation crisis, and characterised by a constant lack of access to the fruits of innovation. The result is increased technological asymmetry between countries, and a huge imbalance between costs and benefits from the public health perspective. By its turn, the report from the "Special Sub-Commission on the Development of the Health Industrial Complex, Production of Drugs, Equipment and Other Inputs" (2014) defends the use of TRIPS flexibilities, the need for increased generic competition, the urgent need to reform Brazilian patent law, and the search for new R&D and innovation models, especially those that de-link R&D costs from the final price of products.

Both reports suggest that the Brazilian government should work on two fronts to fix the innovation and access crisis:

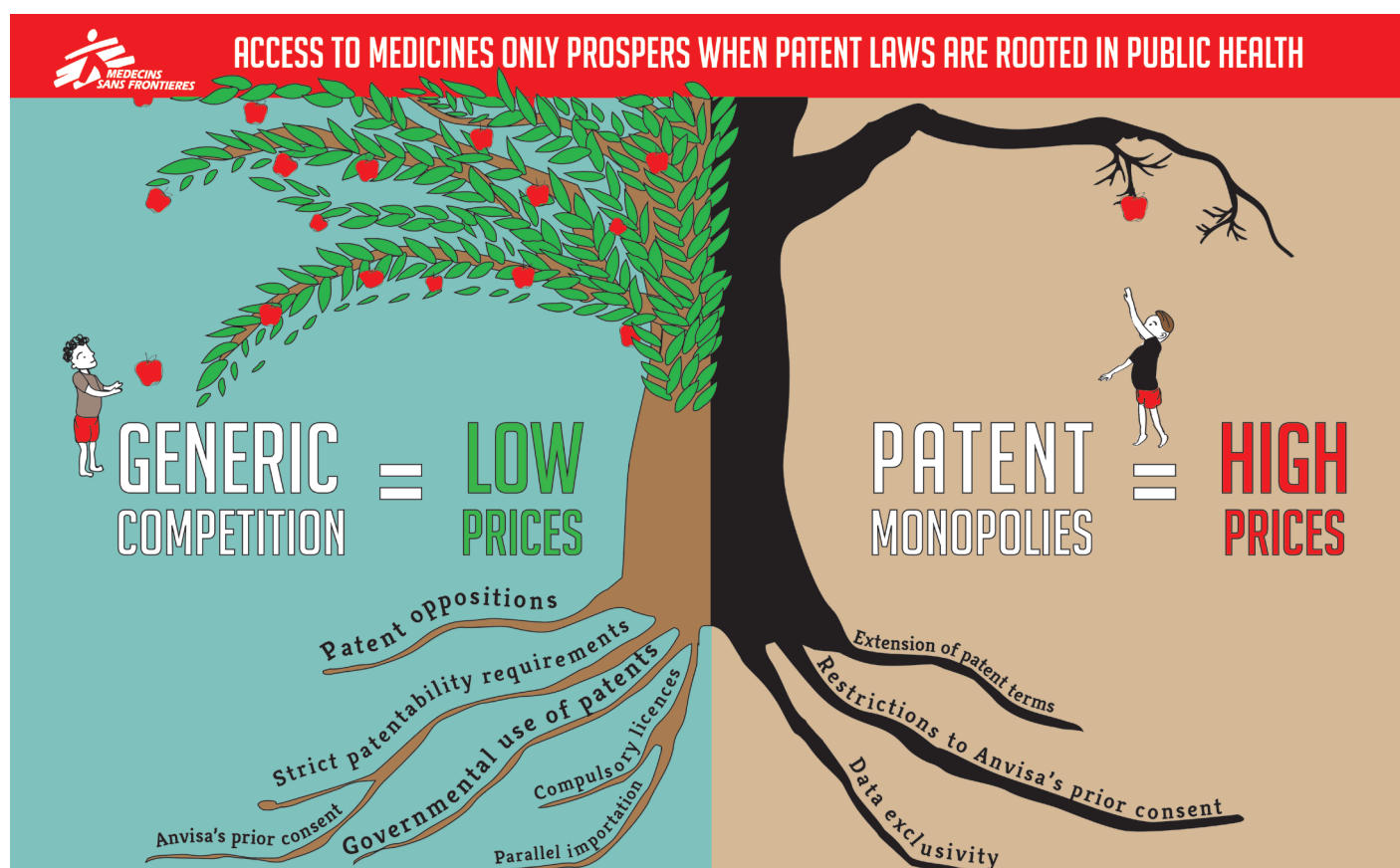
(1) Reduce flaws in the patent system in order to better serve the public interest (see table).

(2) Increase public investment and implement alternative R&D incentives that promote innovation, but also allow for access to affordable medicines (see page 8).

(1) REDUCE FLAWS IN THE PATENT SYSTEM IN ORDER TO BETTER SERVE THE PUBLIC INTEREST

A summary of the positive changes being proposed can be found in the following table:

What improvements can the reforms tabled in Brazilian congress bring?			
Flaws in the current law	Improvements proposed	Bill n°	Outcome
Pre-grant patent oppositions may not be considered by patent examiners	Patent examiners are obliged to recognise arguments presented through pre-grant patent oppositions	5402/2013	Improved public participation in the patent examination process; stronger rejection of undeserved patents
Uncertainty over the role performed by ANVISA on examining patents	Clarify that ANVISA is entitled to analyse the fulfilment of all the patentability requirements established by the patent law	5402/2013 3943/2012	Secure the participation of the health sector in the review of patents, to avoid the granting of underserved patents
Patentability criteria does not detail which kind of pharmaceutical claims are considered innovative or not	List a number of common pharmaceutical claims that cannot be considered innovative enough to deserve a patent	5402/2013 3995/2008 2511/2007	Reinforce the rejection of frivolous patents, for example patents on new forms of known medicines
Limitations on the use of compulsory licences and governmental-use licences to promote price reductions	Remove barriers to the issuance of compulsory licences and strengthen the mechanism allowing governmental use of patents	8090/2014 5402/2013 2846/2011 303/2003 139/1999	Better grounds to address abuses in monopolies, protect public health policies and supply countries without manufacturing capacity
Open channels to extend the monopoly term beyond the standard 20 years	Remove provisions that can lead to monopoly extensions	5402/2013	Ensure that generic competition starts as soon as a patent monopoly ends
Limitation on the use of parallel importation mechanism	Change the regimen to international exhaustion of rights	8091/2014	Allow parallel importing of lower cost patented or generic products put onto the international market



Analysis of provisions under discussion at Brazilian congress

Measures to protect public health

Patentability criteria: Whereas the 1996 law is insufficiently precise in terms of defining what deserves a patent in Brazil, some new bills specifically identify types of pharmaceutical patent claims that may not be considered inventive. These provisions directly tackle the industry strategy known as ‘evergreening’, when multinational pharmaceutical companies apply for secondary patents for trivial changes to existing compounds, so that patents and monopolies can be ever extended, blocking generic competition and limiting supply options for government treatment programmes. By introducing stricter patentability criteria, Brazil will improve its ability to reject and revoke undeserved patents. Experience from countries such as India show that reducing patent barriers enables the local development and use of fixed-dose combinations, which for diseases such as HIV and TB are critical to provide patients with effective, easy-to-take combinations. Strict patentability criteria is also a way to encourage companies to focus on developing new medicines, instead of seeking patents on minor modifications to existing products.

Pre-grant oppositions: A proposed amendment would make it mandatory for patent examiners to respond to oppositions that are filed, thereby formalising the pre-grant opposition proceeding. Such a change would enable Brazil to capitalise on the experience gained from cases such as the tenofovir opposition, and to strengthen the opposition mechanism so that it is a more effective tool serving the public interest. This is in line with Brazil’s position at WTO calling for strengthening of opposition systems.

ANVISA prior consent: Involving the Ministry of Health in the examination of pharmaceutical patent applications has been recognised as an innovative and effective mechanism under Brazil’s patent system from the perspective of safeguarding public health needs of the country. By clarifying the patent law, Congress can secure ANVISA’s involvement in the analysis of patentability requirements and other

criteria already established by law, and ensure that patent applications not approved by ANVISA are in fact rejected.

Compulsory licences and government use of patents: Brazil currently lacks an explicit mechanism for governmental use of patents, although it does already allow compulsory licences. Authorising the public, non-commercial use of a patent by government agencies will allow public interests to be prioritised more quickly. This provision is fully in line with TRIPS obligations, and is common practice in many countries, serving as an important tool to balance the private rights of patent holders with the public interest. In addition, it is important that Brazil maintains a wide variety of grounds in patent law for issuing compulsory licences, including those concerning ‘refuse to deal’, anti-competitive practices and other situations, particularly while the balance between patent monopoly and knowledge diffusion is considered broken. One of the bills would also include in Brazilian law the possibility of using a compulsory licence for exportation of patented products (also known as the Paragraph 6 mechanism), namely products manufactured through a patented process, for the purpose of supplying countries with insufficient or no manufacturing capacity. This is an important step towards making full use of all flexibilities available under international trade rules, and would enable Brazilian manufacturers to strengthen access to medicines in other developing countries.

Parallel importation: This flexibility, allowed under TRIPS, enables countries to obtain the best price on the global market for medicines, as it allows imports of a lower cost medicine without the patent owners’ consent, if that product has been put on the market in another country. Parallel importation provisions, however, can be drafted in different ways. In Brazil it was incorporated under a national exhaustion of rights regimen. This model provides greater protection to patent owners than required under international trade rules and in practice allows them to block parallel importing. A proposed

amendment would change the regimen to international exhaustion of rights, which allows for importation of both patented and generic products on the market in any other country. The majority of WTO countries have international exhaustion of rights, and parallel importing has been widely practised by some Western countries. By improving and using this flexibility, Brazil can achieve greater price reductions for a variety of drugs.

Measures harmful to public health

Patent term extensions: Currently, under Article 40 of the 1996 law, the duration of a patent is limited to 20 years from the date of filing the patent application. Nevertheless, the law also allows for compensation for the time spent for examination of the patent application, so that the period of patent protection is longer than 20 years. This is a typical ‘TRIPS-plus’ provision (in that it goes above and beyond what Brazil is obliged to do under the TRIPS Agreement), and one that should be revoked. Indeed, the time needed to complete a thorough substantive examination may be lengthy, but this is a common practice across countries and is not specific to Brazil. Granting patent term extensions not only unnecessarily extends the term of patent protection, but it places undue pressure on patent examiners that have to review thousands of frivolous patent applications filed by multinational pharmaceutical companies.

Data exclusivity: Through data exclusivity, multinational pharmaceutical companies can delay generic competition by preventing a national drug regulatory authority from relying on original test data to establish the bioequivalence of a generic medicine. This is not required under the TRIPS Agreement, which only requires protection of undisclosed data in the context of unfair competition. Some bills propose that no data exclusivity is allowed during the drug registration procedures. By rejecting data exclusivity, Brazil’s patent law could ensure the monopoly position of originator companies is not unfairly prolonged through regulatory procedures.

(2) INCREASE PUBLIC INVESTMENT AND IMPLEMENT ALTERNATIVE R&D INCENTIVES THAT PROMOTE INNOVATION AND ACCESS TO AFFORDABLE MEDICINES

Since at least 2001, Brazil has been actively pushing for resolutions and decisions that highlight the problems in the patent system, and calling for solutions. The *Global strategy and plan of action on public health, innovation and intellectual property*, which was approved at the World Health Assembly in 2008 under a strong leadership from Brazil and other UNASUR countries, has paved the way for the current debate at WHO on new innovation models.

In order to continue this leadership at the global level, Brazil should take action at the national level to implement the recommendations in *Brazil's Patent Reform: innovation towards national competitiveness* (2013) and the "Special Sub-Commission on the Development of the Health Industrial Complex, Production of Drugs, Equipment and Other Inputs" report (2014), which are:

- a) Creation of a national health innovation prize, to stimulate research under a non-exclusivity regimen, placing results in an open access platform; and
- b) Create a fund for priority health needs that accounts for at least 0.01% of GDP.

MSF perspectives on the National Prize:

The report from the "Special Sub-Commission" recommends that the Ministry of Health establish a health innovation prize in Brazil. MSF suggests that efforts could begin with the definition of a clear prize target in terms of a priority health technology. As 'pull' incentives, prizes pay for R&D efforts on the delivery of results; rather

than conferring monopoly rights as an incentive, prizes pay out in full as soon as the milestone is reached, allowing for immediate dissemination of the new technology at fair, competitive prices. The aim of such a prize would be to demonstrate how alternative incentives to monopoly rights can work in practice. It would be a 'test case' in order to learn from the experience and pioneer new models.

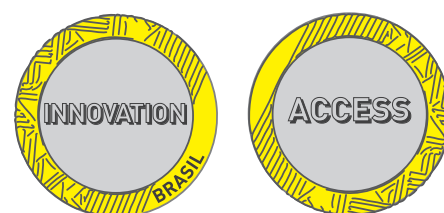
MSF perspectives on the National Fund:

In line with the *Brazil's patent reform* report's recommendations, the research results stemming from any increased public financial contribution should be placed in the public domain or made available through a mandatory open access platform. The report further recommends that research priorities be coordinated and defined by the Ministries of Health, and Science, Technology and Innovation. MSF would add to this the importance of coordinating with WHO to ensure global coherence. Moreover, MSF would like to stress that attention should be paid to the whole innovation cycle, so that R&D efforts support the eventual delivery of affordable and accessible health tools on the market, rather than focusing exclusively on funding to 'de-risk' R&D efforts by supporting early stage R&D.

In demonstrating a strong commitment to the R&D needs of developing countries through increased financing, and demonstrating how alternative incentives work at the national level, Brazil will be in

a position to lead discussions globally on how these incentives can be refined and brought to scale.

Much of the R&D behind successful new drugs is heavily subsidised by the taxpayer. Globally, at least 40% of all R&D is paid for from the public purse and by philanthropic organisations. Despite the use of public funding for new treatments, governments and individuals are often then faced with high prices for medicines, secured by the patent regime. In effect, people are paying twice for new drugs. And in many cases, this investment results in the neglect of non-lucrative health needs and exclusion of patients who cannot afford the increasingly expensive treatments that industry chooses to develop. The medical innovation system is broken – it's time we fixed it for the benefit of everyone. We urgently need an alternative system, one where R&D investments result in needs-driven innovation and access. Leadership from countries like Brazil will be critical in reconciling medical innovation with its original purpose: to achieve better medical outcomes and ensure the fruits of science are equally shared.



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MSF Access Campaign

Médecins Sans Frontières, Rue de Lausanne 78, CP 116, CH-1211 Geneva 21, Switzerland
Tel: + 41 (0) 22 849 84 05 Fax: + 41 (0) 22 849 84 04 Email: access@msf.org

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