Challenges for the universal access to medicines in Brazil – brief comments from civil society[1]

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1. Introduction

In Brazil, the right to health was established in 1988 Federal Constitution as a right for all citizens that should be provided by State through social and economic policies. This was the basis for the formulation and implementation of the Unified Health System (SUS), a public system which considered the universality of access to health services in all levels, the integrality of care, the equality of care – without any kind of prejudice or privileges -, the community participation, and a decentralized management.

Access to treatment, including pharmaceutical services, is part of the SUS implementation. One of the legal framework related to treatment is the National Medicines Policy (Decree 3.916/96), which is a long term commitment that takes into account strategies to guarantee access to quality medicines for the population.

In the case of HIV/Aids epidemic, there is also the Act 9.313/96 which guarantees the integral access to treatment, including both antiretrovirals (ARV) and medicines for opportunistic infections (OI). After this act was signed there has been a considerable expansion of the number of people having access to ARV as a pillar of the aids programme. There has also been a strong commitment of the National Aids Program as a whole since that decree. The local production of ARV by both public and private national companies has been crucial to provide government with cheaper generic version of non patented drugs in Brazil. This was possible because Brazil did not grant patents to pharmaceutical products and processes.

However, in 1996 Brazil also changed its Industrial Property Act in order to becomeTRIPS compliant. The transition period allowed by TRIPS for pharmaceutical products was not used and the country started granting patents for pharmaceuticals in 1997. The Brazilian legislation went much further that what was required by TRIPS and included a *pipeline* provision, where patents claims could be filed in the country between 1996 and 1997, allowing the protection of pharmaceutical patents that were already filed in at least one other country, without any national examination and even if the patent was prior to TRIPS signature, as long as the product was not yet commercialized anywhere or nobody has done efforts to in the country for exploration at the time of the request.

Since then, several challenges have emerged in order to guarantee access to medicines policies, the main one, being the increase in the cost of the treatment because of newer medicines subject to patent, not produced nationally and recommended by national guidelines to substitute or complement earlier treatment protocols. This is in addition to the increase of the number of patients on ARVs.

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[1] Text written for the International Conference on Compulsory Licensing: Innovation and Access for All", 21-23 November 2007, Bangkok, Thailand (http://www.cl4life.net). The authors would like to thank Michel Lotrowska for the revision.

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2. Public health TRIPS flexibilities in Brazilian legislation and the use of Compulsory License

From a public health perspective, Brazilian industrial property legislation did incorporate some of the TRIPS flexibilities such as compulsory licensing and the *Bolar*[4] exception. The legislation also included the "experimental use" and the "prior consent" mechanism within the Brazilian health regulatory authority[5] which allows them to analyze and decide the patentability of pharmaceutical patents claims filed in Brazilian Patent Office (INPI). This mechanism aims to avoid the granting of non-innovative patent claims based on simple increments.

The full implementation of compulsory license (CL) has been supported by Brazilian civil society for the past years as a way to overcome sustainability threats imposed by high costs of medicines.

However, this flexibility was only implemented in 2007. From 2001 to 2003, the CL was used as a threat to lower prices during negotiation between MoH and multinational pharmaceutical companies, for products that were accounting for 60% of MoH ARV budget, such as lopinavir/ritonavir, efavirenz, and nelfinavir. This was possible because the public laboratory *Farmanguinhos* could set the cost of production of some products, providing government with bargaining tools.

In 2005, during another round of price negotiation with Abbott, on lopinavir/ritonavir, used at the time by 17.000 people, the government went one step forward towards CL, declaring through an official decree that the medicine was of public interest and gave 30 days to the company to reach a lower price. After some months of negotiation, the same Minister of Health made a deal with Abbott, accepting a fixed price of 1.380 US$ per year per patient until 2011 regardless of the increase of demand, or international variation of prices, also giving the guarantee not to use compulsory license on any of the patents related to the product. This was considered by some civil society groups as a bad deal and clearly a TRIPS-plus type of deal.

The deal showed clearly of the lack of public health safeguards in the country legal framework to protect public health and more especifically the access to medicines policies.

After the agreement between government and Abbott, non-governmental organizations (NGO)[6] members of the Working Group on Intellectual Property of the Brazilian Network for the Integration of Peoples (GTPI/Rebrip) filed together with the Public Attorney a civil public suit in Court against both the government and Abbott demanding the issuance of a compulsory licensing for lopinavir/ritonavir. The fast-track demand of the process was rejected because the Court argued risk of retaliation from developed countries, risk of lack of supply and lack of local capacity to produce medicines.

At the same time, the National Health Council (social control of the Unified Health System) composed of elected members coming from all segments of society for 50 % and from government bodies for the other 50 % voted unanimously a motion requesting the Minister of Health to issue the CL.

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[4] Allows reverse engineering of a patented product before the end of the patent and also registration of the product at the Drug Regulatory Authority, which in the case of Brazil is ANVISA. It doesn´t allow commercialization of the product unless there is a Compulsory License.

[5] In Brazil, pharmaceutical patent claims must be submitted to Brazilian Drug Regulatory Authority (ANVISA) for prior consent on patentability and then come back to Brazilian Patent Office (INPI).

[6] ABIA, Conectas Direitos Humanos, GIV, Grupo Pela Vidda/SP, IDEC, GAPA/SP and Gestos

For these reasons, in 2006 the GTPI, supported by Medecins Sans Frontieres, (MSF) contracted national and international experts to assess of the technical capacities of four laboratories (two publics and two national privates), which proved the local capacity of Brazilian laboratories to produce first and second line ARV[7]. These results were also proved by two other concomitant studies developed in Brazil by Clinton Foundation and United Nations Development Program (UNDP).

Also in 2006, the GTPI members tried to use administrative channels in order to avoid the granting of unreasonable patents for essential medicines in the National Patent Office (INPI), one of which is a second patent for lopinavir/ritonavir by Abbott.

Civil society groups are considering the Court a potential channel to defend collective rights because: (a) it is a way to find alternatives inside the current patent system in force in Brazil; (b) it is a way to raise public awareness on the negative implications of intellectual property rules on access to health; (c) it is a way to stimulate and involve the Judiciary level to take measures to pressure the Executive level to implement public health flexibilities.

In 2007, the MoH gave one more step ahead and finally issued a compulsory license for efavirenz. The cost per patient/year was US$580 since 2003, while on the international market, it was possible to find prices twice as low. After negotiating several times with Merck, the only offered reduction was of 2%, which was unacceptable. For example, this was twice times higher than the price offered by Merck to Thailand after the country issued the compulsory license for the same medicine.

Efavirenz was declared of public interest in April and the compulsory license was issued in May 2007. While the local production is being developed by two public laboratories (Farmanguinhos and LAFEPE), the generic version is being imported from Indian pharmaceutical companies at a third of the Merck price (US$144 per patient/year).

Some lessons could be learnt from this important experience toward public health protection. The first one was the strong support provided by civil society groups in this implementation process of compulsory license. Many groups have been pushing for the implementation of public health flexibilities, as part of the HIV/Aids and health's movements agenda. There was much pressure in the mass media, against the measure taken by the government, but many groups could support the public interest and the importance of the measure as well. Also, there has been a great international supports for the measure taken. Second, the Brazilian government is committed with universal access to health and to treatment. Third, the important precedent opened by Thailand in issuing compulsory license was an incentive for Brazil. Fourth, the existence of more than one offer on the international pharmaceutical market of the medicine compulsory licensed, which reduced the possibility of lack of supply.

However, this is not an ended battle and there are more barriers to overcome when we look deeper into the Brazilian patent system related to the protection of pharmaceutical patents. It is already known that the costs of new ARV are increasing and accounting for most of the MoH ARV budget.

[7] Fortunak, J. M.; Antunes, O.A.C., 2006.*The ARV production in Brazil – an evaluation*. Rio de Janeiro:ABIA/MSF. Available at: http://www.abiaids.org.br/media/ARV.pdf

3. Limitations in Brazilian Patent system and negative impact on health

There are some internal problems both in the patent legislation and in its implementation that can hamper public health, which we would like to highlight the following:

- Pipeline provision
- Difficulty to implement the MoH role in the process of analyzing pharmaceutical patents
- TRIPS-plus provision under vote in the Brazilian Congress

Pipeline provision

The pipeline provision constitutes a temporary provision whereby patent claims were accepted for technological fields that were not previously recognized (from May 1996-May 1997), allowing for the granting of patent protections for pharmaceutical and food products, among other things. Pipeline patent claims would only be submitted to a formal analysis and would follow the requirements of the patent conceded in any foreign country. They would not be submitted to the Brazilian Patent Office (National Institute of Industrial Property, or INPI) for a technical evaluation of whether the product meets patentability requirements – novelty, inventiveness and industrial application.

They had a great impact on important areas of social interest, as well as on the country's technological and economic development. Patent protection awarded through the pipeline provision means that protection where monopoly was granted for inventions already in the public domain, as they had been previously published in foreign countries.

The ARV Efavirenz, for which the Brazilian government recently issued a compulsory license, is protected by a patent obtained under the pipeline mechanism (priority date of 92). In other words, when this patent claim was filed in Brazil, the novelty requirement did not exist anymore (since the invention information had already been published five years earlier). Had the pipeline patent not been granted, this active ingredient could have been produced in Brazil, as it was in India.

Other medicines that are fundamental in order to face the HIV/Aids epidemic, such as lopinavir/ritonavir, abacavir, nelfinavir, amprenavir, were also protected by pipeline, as well as the cancer medicine – imatinib (branded as Gleevec).

Brazilian Patent Office versus ANVISA

According to Brazilian industrial property legislation, pharmaceutical patent claims need the Prior Consent of the Brazilian Drug Regulatory Authority – hereafter ANVISA – based on a public health oriented guideline. Brazilian Patent Office (hereafter INPI) has a broader guideline for examination, which allows the protection of non-innovative patent claims.

Currently, there are two problems in the implementation process of this public health flexibility: a) INPI does not publish negative decision made by ANVISA´s Prior Consent, which means that the patent remains pending and the potential patent holder enjoys a monopoly "de facto" anyway; b) INPI is currently reviewing its guidelines for patent examination by promoting what they call "technical discussions", mainly with the participation of private interest representatives.

TRIPS-plus provision

There is a Bill in Congress (#29/2006) for the inclusion of the TRIPS-plus provision "linkage between patent protection and medicine registration". If approved, it means that the 'Bolar exception' will be annulled. This is a very simple evidence on how TRIPS-plus provisions are trying to make their way beyond bilateral or regional free trade agreement in developing countries. Pharma Lobby influences politicians who fight to change internal laws in a TRIPS-Plus way. So it is important that we can implement the positive achievements of Brazilian government in maintain pro-health safeguards in the scope of international arena, such as WHO and WIPO, into the national level.

4. Challenges for implementing public health TRIPS flexibilities: civil society perspective

There are a set of challenges faced by civil society when trying to keep the universal access to medicines policies above intellectual property rules, which include both finding alternatives inside the current patent system in force to implement TRIPS flexibilities, and also the monitoring of the international discussion on 'innovation and access' in the scope of World Health Organization Intergovernmental working group on public health, innovation and intellectual property (IGWG).

There is an ongoing challenge on incorporating the international discussion as well as patent problems of newer medicines in the national agenda of civil society groups and social movements. One of the ways to do this is by constant discussion and information sharing of these issues during specific national meetings. We believe that to act at the international level, we need to strengthen the internal agenda on the same issues.

Another important challenge can be seen under two angles: a) product-by-product perspective; b) the national patent system.

The first one is related to the constant monitoring of new medicines being included in the guidelines, as well as their barriers for access. We believe that it is very important to strength developing countries cooperation, since we will probably be facing the same problems for the same medicines.

The second one is related to the whole national system and its impact on health policies, such as the above mentioned cases. This broader perspective represents structural challenges for the constant implementation of health policies.

Again, we believe in the importance of the strengthening of civil society group of their networks in order to improve the interchange of experiences, to mutually support national problems, as well as to find collectively alternatives against the negative impact of patents in access to health.