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Activities 2013-2015



## Latin-American Network for the Access to Medicines

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# **RedLAM Systematisation**

## **2013-2015**

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Latin-American Network for the Access to Medicines

[www.redlam.org](http://www.redlam.org)

### **General Coordination**

María Lorena Di Giano

### **Consultant**

Marialba Endelli

### **Print Design**

José Luis Peralta

### **Collaboration:**

María Lorena Di Giano, Francisco Rossi, Roberto López Linares, Anuar Luna Cadenas, Marcela Forgaça Vieira , Monica Di Giano, Felipe Carvalho, Pedro Villardi , Lídice López, Mayra Vásquez, Javier Llamaza, Rosana Di Giano. Miguel Cortés, José Gerardo Cabrera.

## **1. Purposes**

This systematization presentation offers documentation regarding the experiences that place within the organized community in order to promote the use of healthcare safeguards, the leveraging on governments so their decisions guarantee the right and access to healthcare along with avoiding the adoption of TRIP-plus measures. The aim of this work is also to show how the organized community shares information in order to generate an intense experience exchange and collaboration so the good experiences of the middle-income countries of the region can be reproduced. For this reasons, the main purpose of this work is to contribute to the enhancing of the South-South cooperation in Latin America in the matter of access to medicines.

## **2. Patent-generated Barriers**

A patent is a set of exclusive rights granted by a sovereign state to an inventor or assignee for a limited period of time during which the product or process can be commercially exploited, in exchange for detailed public disclosure of the invention. Regarding medicines, this means that there are time and place restrictions for anyone other than the patent holder, who wants to produce or commercialize the patented medicine. This also means that this medicine cannot be purchased in countries where generic drugs are produced (either because the medicine has not been patented, or because the patent has expired, or because of government intervention on behalf of the right to healthcare by means of a compulsory license.)

Patents and exclusive data protection have generated a critical and alarming raise in medicines prices due to the market monopoly that these exclusive rights yield in favor of the patent holder, which consequently means that the right to access to medicines is threatened, as well as the sustainability of state systems that provide medicines in middle-income countries.

In summary, the exclusive rights rendered by a pharmaceutical patent contribute to the stemming of a market monopoly that spawns negative consequences such as unmeasurable raises in medicines prices, difficulties for people as well as for countries' access to medicines, and the consequent lack of motivation to continue researching, innovating, producing and commercializing those medicines.

This situation moved Latin American organizations towards a joint effort in order to boost capacities, enhance the citizens' awareness and sense of power, and increase actions of political leverage aimed at securing the right to healthcare and access to medicines through government decisions and policies.

## **3. On Creating RedLAM**

While the network organizations were already joined by informal pre-existing bonds, the Latin-American Network for the Access to Medicines (RedLAM), started its joint activity formally in December 2012, thanks to the initial support of the Robert Carr Foundation- RCNF.

Since then, the network comprises the following organizations: Acción Integral para la Salud (AIS) from Peru, Fundación IFARMA from Colombia, Fundación Grupo Efecto Positivo GEP Argentina, Associação Brasileira Interdisciplinar de AIDS ABIA and Grupo de Trabajo sobre Propiedad Intelectual GTPI from Brazil and Red de Personas Viviendo con VIH from México.

These networks and member organizations of RedLAM, have great local as well as national experience in access to treatments and services for HIV/AIDS, and particularly in access to medicines and the relation with intellectual property. They have also been working in a regional, non-structured collaboration for many years. The RCNF support in 2012 has enabled RedLAM to work systematically as a regional network.

RedLAM was structured with the purpose of helping eliminate the barriers to the access to HIV and Hepatitis C medicines. Such barriers are the unfortunate consequence of property rights and other exclusive rights. The network's efforts are aimed at: a) increasing public awareness of the need to secure the sustainability of programs that provide medicines for HIV-AIDs in Latin America; b) enhancing the capacities of activists and the civil society, especially the young people, to monitor and positively influence on public policies; c) leveraging on the public debate on intellectual property subjects from a human rights perspective; d) improving public policies to prevent or mitigate the negative effects of intellectual property rights on the access to medicines in Latin America; and e) boosting the South-South cooperation in the region so that access to treatments for HIV-AIDS, opportunistic infections, co-infections and Hepatitis C is made possible.

The implementation of the Network has been the first accepted challenge, by assigning some features that helped consolidate the network and secure its sustainability and effectiveness throughout the years.

**Initial stimulus and Network model.** The initial funding provided by the RCNF was proven to be utterly important for the Network founding. It also made possible the generation of other action schemes. The network as a way of working was chosen and the General Regional Coordination on part of GEP Foundation (Fundación Grupo Efecto Positivo in Argentina) was democratically decided.

**The Network Structure.** As a network, it has not adopted a rigid structure. Each node iterates between coordination and executive roles depending on its activities. This has been a critical factor in enhancing the coordination and executive abilities of each node. It has also helped distribute responsibilities and increase the organizations' level of involvement in RedLAM activities, therefore contributing to homogenously strengthen the Network.

**Sorting out the tension between regional and local.** The Network has a regional vision of the issues, shared purposes and a consensual approach strategy, but its activities are discussed at a local level, in order to be adapted to the realities of the participating countries. In this way, the Network has accomplished a balance between regional needs and local realities, which do not always correlate.

**Decision-making process.** Democracy: each node is autonomous, has a full right to vote and the same conditions as the rest of the nodes, regardless of its coordination power during a given activity.

**Creating meeting workspaces.** The Network has been able to work successfully through the use and hiring of virtual platforms, the setup of a website [www.redlam.org](http://www.redlam.org) and a Facebook page “Red Latinoamericana de Acceso a medicamentos”. Thus, meetings have been encouraged, there has been information exchange, and forums and debates have been generated. These instruments have consolidated the internal Network communication, as well as the external, with the participation of activists, involved populations and experts in the subject.

**Communication: clear and horizontal.** Horizontal and inclusive discussions taking place through virtual platforms (WeBEX-Skype) and e-mail have contributed to a democratic performance of the Network as well as to the acquisition of knowledge by the members of every organization. This has been successful thanks to open virtual spaces.

The Network structure and its specific organization and performance features have undoubtedly been among the main achievements of RedLAM.

#### **4. Access to Medicines and Intellectual Property**

In 1994 a new organization was created with the purpose of establishing global trade regulations: the World Trade Organization (WTO). Such regulations were adopted in a number of Agreements ruling on different trade areas.

Previous to the implementation of the Agreement on Trade-Related Aspects of Intellectual Property Rights, (TRIPS), most of developing countries did not grant pharmaceutical patents. But since the implementation of this Agreement, the member states of WTO have had to adjust their national legislation due to their commitment to uphold the Agreement. Therefore, national rules were issued in order to protect intellectual property rights (IPR), making available the granting of patents in every technological field, including pharmaceutical products. Since then, a chaotic behavior in the medicines prices has been witnessed. The patent system generates a *de facto* monopoly at the sole existence of a patent application and a legal monopoly on a product or process once the patent is granted, resulting in an arbitrary setting of prices varying from one country to another (even if they share the same patent or data protection conditions) regardless of the disease or the market size. Prices are undoubtedly high reaching values that, in the case of

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HIV/AIDS medicines may be 60 times higher than the price of the generic drug<sup>1</sup>.

**I**n countries where there are systems that guarantee the right to healthcare and the universal access to medicines, the rise in prices has jeopardized the sustainability of public programs that provide medicines and the stability of these policies. In the case of HIV/AIDS, the access to first-line treatment has been made possible thanks to the production of much more affordable generic versions. But, unfortunately, when the time comes to change to the second and third-line treatment, these medicines are protected by Intellectual Property Rights, making the production and acquisition of generic versions impossible.

In this sense intellectual property rights are an obstacle for healthcare , especially in countries that are able to produce the medicines locally, but are prevented from doing it by patents that are usually extended through *evergreening*. The patent system grants its owner an exclusive right so no one else can produce and commercialize the patented product for 20 years. When this term is close to its expiration date, laboratories make slight changes in the same medicines in order to apply for a new patent which is usually granted for 20 more years. This impacts negatively in the access to medicines since generic versions cannot enter the market.

**B**ecause of the amount of resources involved, the pharmaceutical industry has become one of the main worldwide businesses with the ability to weaken the countries' national sovereignty: high prices and lack of control over them, make it impossible for countries to seriously provide for their populations' healthcare, mainly because most of the countries involved are middle-income countries with high levels of poverty. Besides, it is these billionaire practices that increase the gap of inequality among countries. A proof of it is that 95% of medicine patents in Latin America belong to developed countries.

Laboratories pressure on governments to increase the protection of intellectual property rights has increased over the past decade. This has been done through the adoption of TRIPS- plus measures that prevent the use of flexibilities and healthcare guarantees that had been stated in TRIPS as the countries' rights to protect the people's right to healthcare and access to medicines (compulsory licenses or the possibility to determine the criteria to define the requirements for

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<sup>1</sup> International reference price in India: "Untangling the web of antiretroviral price reductions, 15 th editon, July 2012." See "Estudio comparativo de precios en Argentina, Brazil, Colombia, México y Perú (Comparative study of prices in Argentina, Brazil, Colombia, México and Peru) -Redlam, 2015.

TRIPS art. 8 .1 "Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement."

patentability stated in TRIPS) This pressure presents itself in different ways, especially through bilateral agreements, like the FTA between Colombia and Peru with the USA and the EU. There is also pressure at national level, since countries are constantly summoned to change their legislations for these to contemplate those agreements.

In most middle-income countries in Latin America –the continent where inequalities and poverty have reached the highest levels in the world –, the impact in public health generated by the protection of intellectual property is particularly critical and a source of serious concern about the near future, so public programs that were created for the sake of providing universal access to medicines to fight epidemics are having a hard time to work efficiently.

### **5. Activities that have been developed by RedLAM**

During these past two and a half years the Network activities have been developed around the following core ideas: 1) To recover and generate knowledge about intellectual property and the access to healthcare through documental study and research; 2) To improve the abilities for political influence through the strengthening of civil and community society; 3) To implement concrete actions of political leverage; 4) To use healthcare safeguards; 5) To promote social action that helps realize the negative impact of intellectual property on the access to treatment and its real consequences for public health; 6) Noticeability of RedLam's position and actions.

#### **a. Activities aimed at showing the relationship between the access to medicines and intellectual property.**

The intellectual property rights system works as a power device designed to keep the knowledge (on how medicines are made) and the extraordinary profits of pharmaceutical monopolies. In this context, it is critical that we recover and generate knowledge, since this allows us to develop and collect evidence that will help us in political leveraging, in fighting the necessary legal battles, and in renewing the material that will enhance our activists' capacities. We must undoubtedly be able to know what the laboratories hide in order to tell the truth. This is why some of the Network activities consist in studies, research, data analysis and information tracking, since this knew knowledge enables us to state claims against what the dominant knowledge –the laboratories'- is hiding. Thus, the following research activities have been developed:

**Research study on antiretrovirals and how they are related to the protection of intellectual property rights.** The purpose of this study was to put under analysis the prices of antiretroviral treatments for HIV AIDS in the five mem-

ber countries of RedLAM and to evaluate its relation with the protection of intellectual property rights in each national context. For this purpose, there was a selection of antiretroviral distributed in each country's treatment, taking into consideration the situation of the patents, the treatment regulations at national level, and the prices of public purchases. Measurements were made on these drugs coordinated by the teams in Peru and Colombia.

### Some findings of the case study

- ✓ **The price of the original medicine can be 65 times higher than its generic counterpart, which means that for every tablet of the original, 65 people can be treated with the generic version.**
- ✓ **On the contrary, the price of a medicine can reach half of the international reference price in a situation where the lack of the protection provided by patents and plurality of suppliers coexist.**
- ✓ **Argentina pays, in average, 25 times the international reference price for each unit of antiretroviral; this is the highest price paid by the countries under study. It is followed by Mexico and Peru at an intermediate level, paying an average of 14 times for an antiretroviral unit. In Colombia and Brazil, which usually pay the lowest prices, the average price is of 4 and 5 times the international reference price.**
- ✓ **In most of the antiretroviral of the selection, the prices in Argentina are the highest paid in comparison with the rest of the countries under study, this having no relation with the number of people under treatment.**
- ✓ **In comparison with the five countries under analysis, Brazil has the lowest prices for antiretroviral medicines.**

### Information tracking on access to medicines and intellectual property.

RedLAM has produced, gathered and shared documents which provide a clear and simple approach to the topic. Such documents intend to generate public awareness, mobilize collective action, enhance the capacities of the regional teams, and to transfer knowledge to the populations involved, as well as to those workers and activists of the HIV/AIDS cause in Latin America. The documents can be found in the Network's website as well as in each organization's website.

In <http://www.redlam.org/> RedLAM published a study about the good practices in the application of patents under examination. This study was aimed at collecting evidence about the good and bad practices applied to patents under examination. For this purpose, a research protocol was developed by professionals from all the member countries of the Network. One of the results of the study was the need to promote pro-health patentability requirements in Latin America. A team of researchers from Argentina and Brazil was in charge of the coordination of the research.

Document estimating the impact of TTP Trans-Pacific Strategic Economic Partnership in the access to medicines based on available data from the Public Citizen website. The main results are shown in the following table. The different types of intellectual property protection are exposed together with the cost of every action in different countries. The equivalence between those costs and the yearly outlay in public health measured in number of people is also shown.

Type of protection for intellectual property rights	Peru		Colombia		Chile		Totals	
	US\$/year	Equivalence (1)	US\$/year	Equivalence (1)	US\$/year	Equivalence (1)	US\$/year	Equivalence (1)
Patenting of new pharmaceutical uses and preparations	32.800.000	113.000	18.000.000	55.000	34.000.000	32.000	84.800.000	200.000
Preventing of oppositions to patents	42.000.000	145.000	42.000.000	127.000	26.000.000	25.000	110.000.000	297.000
Providing exclusive rights to data and previously approved formulae	16.000.000	55.000	20.000.000	62.000	9.500.000	18.000	45.500.000	135.000
<b>Cost of intellectual property rights year-basis</b>	<b>90.800.000</b>	<b>313.000</b>	<b>80.000.000</b>	<b>244.000</b>	<b>69.500.000</b>	<b>75.000</b>	<b>240.300.000</b>	<b>632.000</b>

(1) Equivalence to the yearly outlay in public health measured in number of people.

## b. Activities aimed at boosting political leverage:

Upon consideration of the challenge that medium and long term antiretroviral therapy means for middle-income countries, the following strategies have been identified and developed:

### i. National Workshops

Especial workshops took place in Brazil, Argentina, Mexico and Peru during 2014. These workshops, of broad turnout, developed important work regarding the right to healthcare, access to medicines and intellectual property. Their implementation had the following outcomes: a new work team and a research proposal in Mexico, activities aimed at raising awareness of the negative impact on the access to healthcare of the patent of atazanavir in Peru, and a network of organizations and the planning of actions aimed at securing healthcare in Argentina. A total of 80 activists from 15 organizations took part on the workshops.

### ii. Online Training for Activists

Online courses on Access to Medicines and Intellectual Property have been an excellent tool to get to geographically dispersed activists, creating a way of enhancing the local centers of action. Two courses were held, one in 2013 and

another in 2014. The call was made through the most popular social networks, and also those of people living with HIV and the ones that promote the fight against AIDS in Latin America. Both calls were utterly successful, gathering 190 activists from 16 countries of the region. They became familiar with legal tools, awareness, political leverage and collective action, aimed at efficiently facing the concentration of the medicines market, intellectual property rights and their consequences for public health and access to medicines.

### **iii. Regional Forum on Policies for the Local Production of Medicines.**

#### **Discussion of options for Latin America**

**K**nowing and having the ability to evaluate the possibility of local production of medicines in the Region is important for the consolidation of the civil society and the capacities of the activists in particular. This is part of a medium term action aimed at providing the market with generic medicines as soon as it is enabled by the law. RedLAM considers that the local production of medicines will have an impact on the prices of the original ones because there will be competition within the market. The Network also seeks to recover national independence on medicines supply for the Latin American states, and to secure the access to medicines and the continuity of universal policies for the access to healthcare. This position is aligned with the promotion of public health and the guarantee of the people's right to healthcare.

#### **c. Promoting the adoption and use of public health protection and legal and political leverage actions.**

RedLAM aims its efforts to the accomplishment of national and regional actions to increase the South-south cooperation in Latin-America in matters of access to medicines and intellectual property barriers. This fight, developed at both legal and political levels, is of great importance, since it supports the cause of promoting the adoption and use of public health protection in every country and it aims at identifying key actors and opportunities that will enable the development of actions of political leverage in the national political territory. These local strategies seek to support and promote medicines as a social asset rather than a commodity, to guarantee the right to healthcare and the access to medicines, and to recover the national sovereignty in health matters. These are the reasons why the organizations members of RedLAM have developed the following activities:

#### **i. Use of public health safeguards:**

**In Argentina: Opposition- call to attention on TDF+FTC+EFV,** submitted before INPI. This drug is commercialized under the name **Atripla ®** by Bristol Myers Squibb, and its patent is now in the revision

stage. The drugs lack novelty and inventive activity, so there is a claim against the patent application since this is an essential medicine in the treatment for HIV/AIDS and the prices are too high for the government to provide the therapy.

**In Argentina: Opposition- call to attention on Truvada ®** submitted before INPI, stating a claim against its patent application. Truvada ® is an essential drug for the treatment of HIV/AIDS, it has exclusive rights in the market, its prices are extremely high for the government to afford the treatment, there are other laboratories interested in producing it and its generic versions are not allowed. Besides, upon the analysis of the patent application for TDF + FTC submitted by Gilead Sciences Laboratories it was concluded that such application does not meet the patentability requirements, since it is a composition, combination and formulation of two well-known active components and presents neither novelty nor inventive activity. A study performed by RedLAM on the prices of the medicine in five Latin-American countries found that Argentina spends, in a year of Truvada® treatment, the equivalent to almost 24% of the National Office of AIDS and sexually transmitted infections (DNSyETS in Spanish) annual budget for the purchase of medicines.

**In Argentina: Opposition- call to attention on Sofosbuvir, (Sovaldi®)** Gilead Pharmasset LLC applied for the right to patent and subsequent commercialization of this treatment, which has been shown to be the most effective (90% cure) against Hepatitis C. An opposition was presented against the application, on account of its not meeting the patentability requirements of the law. This drug is essential in our country since almost 800.000 people are affected by Hepatitis C (2% of the population), but its price is unaffordable: US\$ 84,000 in the United States for a 12-week treatment. An urgent resolution was also requested since this drug does not only mean the CURE of the disease, but because its high price could jeopardize the Public Health system in Argentina.

**In Colombia: Compulsory license application for Kaletra ®** (lopinavir + ritonavir) This is a drug manufactured by Abbott, and it was requested to the government of Colombia to issue a compulsory license on account of its high prices.

**In Peru: Compulsory license application for Atazanavir.** In December 2013 a letter was sent to the Minister of Health in Peru to communicate the concern of the Peruvian civil society for the dominant and therefore abusive status of Bristol Myers Squibb in the market. This laboratory commercializes the drug Atazanavir under the commercial name of Reyataz® at 36 times the price of the drug's generic version in Bolivia. In this same letter it was requested to the Minister to declare the public interest of Atazanavir and to therefore issue a compulsory license.

## ii. Political leverage actions

**Intervention in the reform of the Law of patents in Brazil** with the purpose of introducing a human rights perspective in its patent legislation. This was achieved through meetings with Members of Parliament, identification and revision of reform projects of this law and the proposal of a new one that prioritizes the right to healthcare above the commercial rights, engagement of academia and the civil society in the reform process, elaboration of outreach materials and leverage of the public debate with public health arguments.

**Intervention in the reform of the healthcare system in Colombia in December 2013** through IFARMA. A public hearing was carried out to explain the reform of the healthcare system of the country and the relation between the access to medicines and the intellectual property system.

**Meetings of political leverage in Argentina.** Fundación GEP met with officials of the patent office INPI to discuss the implementation of the new patentability guidelines approved by joint resolution (Resolution Number: MI 118/2012; MS 546/2012 y 107/2012 INPI) from the Ministry of Health, INPI and the Ministry of Industry. This resolution approved the standards of examination for chemical and pharmaceutical patents and their impact; Fundación GEP also met with officials from the National Ministry of Science, Technology, and Productive Innovation to discuss the role of the Ministry in the promotion of the public production of generic antiretrovirals in the country, and the potential use of public health safeguards to facilitate the access to medicines.

**Meetings of political leverage in Brazil.** ABIA-GTPI met with the president of INPI to discuss the existent issues regarding the standards of examination for pharmaceutical patents, the relationship between INPI and ANVISA (National Agency of Sanitary Monitoring) in analyzing pharmaceutical patents, and the present need to analyze the proposals for the reform of the Law of Patents in Brazil and to propose a reform that prioritizes the population's right to healthcare over the commercial right of the patent holders.

**Public consultation in Brazil.** In January 2014 a public consultation was carried out by the CAMEX (Chamber of Foreign Trade of Brazil) over a commercial dispute with the United States on the subject of cotton. GTPI took part and pointed out the possible reprisals on intellectual property against the United States. The medicines involved were used in the Public Health System (SUS) and commercialized under the patent monopoly of American companies: Lopinavir / ritonavir, darunavir and etravirina (AIDS therapy) erlotinib / HIV (lung cancer therapy) Trastuzumab (breast cancer therapy) and Entecavir (Hepatitis C therapy).

**Right to Access to atazanavir in Peru.** In December RedLAM made, together with associates and allies from regional Civil Society Organizations, an exhortation for the government of Peru to apply the TRIPs

flexibilities, that is to issue a compulsory license on Atazanavir, patented and registered as Reyataz® by Bristol Myers Squibben. The reason to do so relies on the fact that its price restricts the access to the medicine to those who need it the most (according to the results of a study performed by RedLAM in five countries of Latin America, Peru pays for this medicine 36 times the price of its generic version available in Bolivia) This is a consequence of the monopoly granted by the patent, so the exhortation was for the public and private organizations from the countries of the region and multilateral institutions to intervene against the dominant and therefore abusive position of Bristol Myers Squibb; for local producers to provide the local market with generic versions of the drug; and for governments not to give in to the pressures of the pharmaceutical industry which, arguing innovation, squander the government budget.

**Political leverage to keep Prior Concurrence** by means of a document aimed at strengthening the role of ANVISA Brazil (National Agency of Sanitary Monitoring) and rejecting the restriction of its role in the examination of pharmaceutical patent applications in April 2013.

**Urgent request for in-depth examination of the patent application for Atripla (emtricitabina (FTC)+tenofovir ( TDF)+efavirenz (EFV) )** In December 2014, RedLAM presented through FGEP the petition to obtain expedite procedure to prioritize the in-depth examination of the medicine unit dose (processed by Bristol- Myers Squibb and Gilead Sciences LLC y currently in the revision stage at the Patents Office). The petition was presented before the National Administration of Patents in Argentina, taking as antecedent the call to attention presented by that organization in December 2013.

**Written statement to the National Office of AIDS and sexually transmitted infections in Argentina.** RedLAM issued a written statement in Argentina in the World AIDS Day 2014 expressing concern about the high prices that the National Office of AIDS pays for HIV/AIDS and Hepatitis C therapies. It called for public officials to implement lawful strategies that facilitate the price reduction of these essential medicines which currently represents 90% of the budget assigned to this Office.

### iii. Actions that state the position of RedLAM.

**Declaration of RedLAM against the voluntary license for medicines that cure Hepatitis C sofosbuvir and ledipasvir.** This communication of RedLAM exhorts the governments of Latin America to exert their National Sovereignty in Healthcare matters and to make the necessary effort to use the Health Safeguards (flexibilities) included in TRIPS, the Doha Declaration and in our national patent laws, in order to put an end to the dominant and abusive position of the pharmaceutical companies and to guarantee the right to healthcare for those who need urgent access to Hepatitis C therapy. **It is important to stress that Gilead Sciences is not a patent**

**holder and therefore has no exclusive right** since the several patents they have applied for in different countries on the base compound and the prodrug are still pending for granting<sup>2</sup>.

**Letter addressed to Bristol Myers Squibb warning about the high prices of Atazanavir in Peru:** In December 2013, in the framework of the negotiations between the laboratory and the Medicine Patent Pool aimed at the granting of a voluntary license for Atazanavir (essential medicine for the HIV/AIDS therapy), a letter was sent to the managing director of Bristol Myers Squibb calling attention to the abusive pricing of the medicine.

**Request for equal access to treatment to six multinational companies** In the framework of the Hepatitis C World Community Advisory Board Meeting in Bangkok, Thailand, 2014, RedLAM demanded equal access to treatment to 6 multinational pharmaceutical companies. However, AbbVie, Bristol-Myers Squibb, Gilead, Janssen, Merck and Roche refused to provide a plan that could guarantee equal access to the Hepatitis C therapy. Hepatitis C is a curable infection that causes the death of more than 350.000 people a year all over the world.

**World debate on the regulation of biosimilars.** In August 2014 RedLAM took part in the International Conference of Drug Regulatory Authorities (ICDRA). The regulation of biosimilars was in the pre-ICDRA agenda, and the position of the Network was in favor of having just the necessary regulations of biosimilars, including biogeneric drugs, to guarantee the safety and efficacy of the treatments, on the basis that strict regulations and excessive control are the strategies of big companies to extend and eternalize their monopolies.

- ✓ **Positioning and defense of a change in the model of intellectual property**  
In the 67<sup>a</sup> World Health Assembly that took place in Geneva from 19th to 24th May 2014, RedLAM members presented the concept of change in the model of intellectual property, given that the current one is under discussion in developed countries where there is no longer place for innovation.

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<sup>2</sup> In September 2014, GILEAD Sciences signed an agreement with 7 pharmaceutical companies that produce generic drugs in India that enables these companies to produce and sell two of the new antiviral drugs of direct action to Hepatitis C, sofosbuvir and ledipasvir. In this agreement Gilead decided to forbid the sale of these products and its raw material to new licensees. This agreement also excluded 51 middle income countries from the area of geographical application of the license (in Latin America: Argentina, Brazil, Colombia, Costa Rica, Ecuador, El Salvador, Mexico, Panama, Paraguay, Peru). This poses great difficulties for the region to produce generic versions, having the only alternative of purchasing the original versions directly Gilead. Due to the exorbitant prices of the original versions more than 50 million people living with Hepatitis C will not be able to access to the generic versions at an affordable price.

## Monitoring the Free Trade Agreement negotiations

- **Argentina:** in April 2013 a meeting was attended at the Ministry of Foreign Affairs regarding the Agreements that introduce TRIPS Plus measures in the Free Trade Agreement between Mercosur and the European Union.
- **In Brazil:** in February 2014, a meeting was attended at the Ministry of Foreign Affairs where, same as in Argentina, the Network was informed about the negotiations between Mercosur and the European Union, aimed at signing the Free Trade Agreement –FTA containing chapters of intellectual property with TRIPS plus clauses that could seriously affect the right to healthcare and access to medicines.
- **In Peru:** the Network took part of the campaign against TRIPS plus clauses introduced in the Trans-pacific Partnership (TPP) seeking to raise awareness in the negotiators about the impact that these clauses could have in the right to healthcare and access to medicines, and demanding transparency of negotiations.

### d. Promoting social mobilization:

No one says –and therefore a few know-, that in the name of intellectual property rights and for the sake of scientific innovation, the patent system grants 20 years of preposterous profits for companies that within six months get the return of their investment in R+D, for products that have a manufacture cost of less than 1% of their sale price, the investment in publicity being in fact three times the investment in R+D. Intellectual property rights keep their real purpose in pharmaceutical matters hidden: unjustifiable profits. They attack generic drugs since they are competition and threaten their business. Countless advertisements can be found discrediting the quality and efficacy of generics, while at the same time praise the quality and efficacy of their branded counterparts, even when quality control of both products is performed by the same public institution.

RedLAM considers the noticeability of the negative impact of intellectual property rights on the access to healthcare to be utterly important, mainly because of the critical need of raising public awareness about the issue and motivating collective action. Both are tightly bound: awareness motivates action and the noticeability of that action generates even more public awareness. This is the reason why, throughout the years, different approaches have been aimed at accomplishing the Network's purposes: writing and distributing statements, carrying out campaigns and demonstrations, including the issue in the means of communications' agenda, communicating every action, writing and producing documents and statements by the Network, and distributing information exclusively aimed at raising awareness.

**Newspaper article** on Monopoly Abuse published in *La Primera* of Peru, to make public that every intellectual property protection measure, as well as patents, prevent competition since they grant exclusive rights in the market. This can entail “an abuse of the dominant position” as stated in the Constitution of Peru. This abusive behavior is mainly reflected in the high prices of the products under protection.

#### **Informing the civil society of Panama.**

**In August 14th 2013 RedLAM** was invited by the regional office (Panama) from UNDP, to inform the civil society about the perspective on access to medicines and intellectual property in Latin America.

**International Seminar on Access to Medicines** organized by RedLAM and ABIA in Rio de Janeiro, Brazil, with the purpose of giving publicity and expert validation to the comparative study on the prices of medicines.

**Promotion of the debate in Brazil about the reform of the law of Intellectual Property in the National Conference of NGOs working with HIV/AIDS**

**Demonstration against the 17th round of negotiations of the Trans-Pacific Partnership (TPP).** In May 17th, 2013, Peruvian organizations and networks of people living with HIV from different countries of Latin America, organized a demonstration in Lima, Peru, outside the building where these negotiations were being held. This new free trade agreement – in our region includes Chile, Mexico and Peru-, means more protection for intellectual property rights on essential medicines for the treatment of HIV-AIDS and Cancer, among others.

Support to Previous Concurrence in Brazil. A document about previous concurrence of ANVISA, Brazil, was sent to all the members of parliament that are part of the Commission for Economic Development, Commerce and Industry (CEDEIC) in the Chamber of Deputies of Brazil. It was also published in GTPI website.

**Newspaper article** where the organizations that applied for the compulsory license of Kaletra explain the situation.

**Container and awareness on the streets in Lima.** In December 2013, social organizations displayed a 2 metre jar on the street to raise awareness of the high prices paid by the Government of Peru for Atazanavir and to promote the application of compulsory licenses.

**National Campaign in Peru** to raise awareness on the high prices of Atazanavir and the need to issue a compulsory license for this medicine.

*Short film about  
Evegreening in RedLAM  
website and in many  
social networks.*

*Production and  
distribution of GTPI  
bulletins to key  
congressmen and  
members of Brazil's  
Administration.*

*Publication in  
Argentina of the  
previous opposition  
against the patent  
application for  
FTC+TDF+EFV*

#### **Appendix 1 Current status of HIV - Aids and Hepatitis C in Latin America and the Caribbean.**

As of year 2006 almost 1,7 million people were living with HIV/AIDS in Latin America and the Caribbean, two thirds of which live in Brazil, Mexico, Colombia and Argentina. Nonetheless, the frequency of HIV is higher in Central America countries: 1% in El Salvador, Guatemala and Panama, 1,5% in Honduras and 2,5% in Belize; the impact of HIV/AIDS is especially strong in the Caribbean, where 250.000 people live with HIV/AIDS, this infection being one of the main causes of death in adults between 15 and 44 years old.

Among adults in Latin America the prevalence of HIV as of year 2011 is 0.4%, but in more vulnerable populations it is higher: in transgender populations it has been reported that 34% has HIV; in men that have sex with other men it can reach 20,3% and it is higher than 5% in all the countries of the region; in female sex workers it reaches 4,9% -reported by Brazil; but in male sex workers it can reach 22,8%; in injecting drug users (IDU) the prevalence of HIV is above 5%.

In Latin America, HIV slowly progressed between 2001 and 2012: the number of people living with HIV has increased to 15%, new infections decreased to 9%; deaths due to AIDS among adults decreased to 36%; the prevalence of HIV in adults decreased from 0.5% to 0.4%, there was an estimation of 9% less people under 15 living with HIV, new infections in minors decreased 71% and deaths related to AIDS, 50%. However, AIDS is still one of the main causes of death in people between 25 y 44 years old in the Caribbean; in the total of male and female adults living with HIV, as of year 2007 female cases increased 43%.

Antiretroviral treatment coverage varies a great deal in Latin America. It is highly modified depending on the country, but there is also great variability in the methodologies for estimations, the low percentage of people with HIV who took the test and know the result, the barriers for access to assistance, internationally and in Latin America in particular. According to the OMS guidelines from 2010, from the total of people with HIV that need treatment, an average of 51% (45-61%) has access to it. According to information reported by the national healthcare services, 70% of the people have access to it in 9 of 17 Latin American countries. The situation in the Caribbean as described by the World Bank in 2006, shows that with the exception of Cuba, Bahamas and Barbados –countries with high level of access to antiretroviral therapy-, the treatment in the rest of the countries is uneven, and less than 20% of the people who need it have access to it.

Despite the unevenness of the access to treatment and everything that is still to be discovered, the treatment has helped reduce the AIDS cases and the mother-child transmission, plus it has kept the epidemics stabilized.

According to the conclusions reported in the 23th Congress of the Latin-American Association for the Study of the Liver (ALEH), held during September 2014, in Cancun, Mexico, over 185 million people are currently infected with hepatitis C (HCV) all over the world, and approximately 3 to 4 million of infections appear every year. In spite of this, the World Health Organization (WHO) acknowledges that awareness on HCV is low, since only 37% of its member countries have a national plan to control it. Particularly in Latin America and the Caribbean, it is estimated that between 7 and 9 million of adults are infected. In Argentina, over 1% of the population (450.000 people) is infected with Hepatitis C. In the rest of Latin America, the figures of prevalence vary as well, between 1% and 2% of the population, and there are important differences from one country to another. About 80% of the infected patients are asymptomatic, which raises the sub diagnosis of the disease and makes it easier for it to derive in serious hepatic complications. In this sense, less than 10% of patients have been diagnosed, and less than 1% is receiving treatment. For this reason, even though it is a curable disease in 90% of the cases if the right medication is administered, the virus often evolves into chronic hepatitis in over 70% of the cases, and then 20% evolves into cirrhosis and hepatic carcinoma after 20-30 years.

**[www.redlam.org](http://www.redlam.org)**

**Network of Latin- American organizations working together with the purpose of making a contribution to the elimination of the barriers to access to HIV and Hepatitis C treatments generated by intellectual property rights and other exclusive rights.**

**In Latin America, its efforts are aimed at raising public awareness on the need to guarantee the sustainability of the programs that supply HIV/AIDS and Hepatitis C treatment; enhancing the capacities of the activists and the civil society, especially the young people, to monitor and positively influence the public policies; leveraging the public debate on the intellectual property subject from a human rights perspective; and expanding the South- South cooperation with the purpose of contributing to the improvement of the access to medicines in the Region.**

**Fundación Grupo Efecto Positivo in Argentina is in charge of the General Regional coordination.**

**Contact: [comunicacionfgep@gmail.com](mailto:comunicacionfgep@gmail.com)**

**[www.redlam.org](http://www.redlam.org)**

*We are thankful for the collaboration of:*



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