

## Brazil fights for affordable drugs against HIV/AIDS<sup>1</sup>

The access that Brazilians have to affordable essential medicines for HIV/AIDS and other illnesses is under threat because of actions being taken by international pharmaceutical companies and by the Government of the United States of America, according to a report issued in May of this year by Oxfam, an international advocacy group that works to eliminate poverty around the world. In recent months, through its "Cut the Cost" campaign, that group has attracted widespread attention for the issue of medicine prices in poorer countries.

Efforts by Oxfam, Médecins Sans Frontières, and a number of other groups have been key in encouraging international pharmaceutical companies to agree to lower their drug prices for developing countries and in spurring industrialized nations to consider committing more funds for the fight against HIV/AIDS and other illnesses that are common in developing countries. Pressure by Oxfam and other advocacy groups is also considered to have been one of the reasons that in April of this year that major pharmaceutical companies dropped the lawsuit they had filed challenging South Africa's Medicines Act, legislation that the country had approved in an effort to ease the import of cheaper generic drugs.

The new Oxfam report, entitled "Drug Companies vs. Brazil: The Threat to Public Health," says that major drug companies, backed by the United States Government, are trying to ensure that Brazil has to buy expensive patented drugs that the large pharmaceutical firms manufacture, rather than making cheaper generic drugs in Brazil or buying generic drugs from countries such as India. In addition, the report says, the drug companies are resisting tighter price controls on their products that the Government of Brazil would like to impose.

These issues and related ones have been discussed and debated in a number of recent major world meetings, including the World Health Assembly of the World Health Organization (WHO) in Geneva in May 2001. The issues will be also considered in the United Nations (UN), at the General Assembly Special Session on HIV/AIDS, to take place in New York City from 25 to 27 June. Specific disagreements between Brazil and the United States are also being argued before the World Trade Organization (WTO) in a dispute that could have major ramifications for many other countries around the world.

**Key words:** Brazil, acquired immune deficiency syndrome, health economics, drug industry, World Trade Organization.

<sup>1</sup> Based on: Oxfam GB. Drug companies vs. Brazil: the threat to public health. Oxford, United Kingdom: Oxfam GB; 2001. Available from: <http://www.oxfam.org.uk> [Internet site]. Accessed 11 May 2001.

## Oxfam's recommendations on Brazil's access to affordable medicines

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Oxfam is one of several international organizations that have successfully pushed for changes in the worldwide system for selling and distributing essential medicines for HIV/AIDS and other illnesses. Oxfam believes that global patent rules are in need of urgent reform in order to better protect public health in the developing world. With respect to the situation in Brazil, Oxfam is calling on the United States Government and international pharmaceutical companies to stop pressing Brazil to change its policies on medicines and patents. Oxfam's specific recommendations include:

- The United States Government should drop the case against Brazil at the World Trade Organization (WTO). The United States should also stop using "Special 301" investigations and the threat of trade sanctions to oblige Brazil and other countries to institute levels of intellectual-property protection that harm public health and economic development.
- Merck and Roche should not sue Brazil for violations of patents on AIDS drugs. The two pharmaceutical firms should issue voluntary licenses to allow local manufacture of these medicines by third parties, or should agree to sell them at

prices comparable to those of generic manufacturers, such as companies based in India.

- Other industrialized nations should discourage the United States from aggressively promoting high levels of pharmaceutical patent protection. These wealthier countries should also support Brazil's use of compulsory licensing as a last resort in its efforts to ensure affordable essential medicines.
- The countries that belong to the WTO should immediately agree to bolster public-health safeguards in the TRIPS Agreement, including strengthening the right to manufacture or import lower-cost generic versions of vital drugs.
- The TRIPS Agreement should be reviewed, incorporating an in-depth analysis from a development and public-health perspective, with a view to making amendments that: 1) give developing countries greater freedom to decide the duration and scope of pharmaceutical patents and 2) allow countries to require local manufacture of patented products as part of their national development and "health security" strategy.

### BRAZIL SLOWS THE SPREAD OF HIV/AIDS

The WTO dispute and the general issue of pharmaceutical prices in Brazil are also important because of the pioneering work that Brazil has done in its efforts to prevent and control HIV/AIDS. Brazil's achievements have served as a model for other nations around the world, and Brazil has offered to supply other developing countries with advice, technology, and drugs to help deal with HIV/AIDS.

Brazilians are worried that their successes in controlling and treating HIV/AIDS will be reversed

if the country's health service cannot provide affordable medicines to the some 500 000 persons in the country who have the virus. Over the last 5 years, Brazil has achieved much in the fight against HIV/AIDS, including halving the mortality rate, cutting the HIV/AIDS hospitalization rate by 80%, and sharply reducing mother-to-child transmission. The incidence of HIV is also now much lower than UN estimates of several years ago had projected that it would be as of this point.

Brazil's policy of providing patients with free antiretroviral (ARV) drugs has played a significant role in the country's achievements. A key to the

broad public access to ARVs has been the local manufacturing of cheaper generic equivalents of the medicines developed and patented in wealthier countries. By 1999 this approach had cut treatment costs in Brazil by 70% and made it possible for the country to treat many more people than would have been possible otherwise. Taken together, these various steps have saved the Government of Brazil millions of dollars in health care expenses.

## CHALLENGES FROM PHARMACEUTICAL COMPANIES AND THE UNITED STATES GOVERNMENT

One of the challenges to Brazil's dependable, affordable supply of medicines is coming from international drug manufacturers, according to the Oxfam report. The companies accuse the Brazilian Government of excessive efforts to control prices and of not respecting patent rights on drugs for HIV/AIDS and other illnesses.

The second challenge is coming from the United States Government, which in January 2001 asked the World Trade Organization (WTO) to form a dispute panel and hear arguments concerning the United States Government's claim that Brazil's patent law violates international intellectual-property rules. That law has helped Brazil to develop its national pharmaceutical industry and reduce the price of medicines. In addition to its case before the WTO, the United States Government has threatened to impose unilateral trade sanctions on Brazil if the country does not change its patent system.

By putting pressure on Brazil, international drug companies hope to undermine the tough negotiating stance that the country's Ministry of Health has taken on prices for medicines. However, the companies are also concerned that Brazil's example of promoting local production of generic medicines and of using public health considerations to deny companies absolute control over drug prices and patents will spread to other countries. Brazil has taken a leading role in the developing world on the issue of access to medicines, and has raised concerns about how WTO patent rules affect AIDS drug prices. In April 2001, for instance, Brazil presented a resolution to the UN Human Rights Commission on the right to access to affordable medicines in the context of the HIV/AIDS pandemic. Brazil also raised the issue at the WHO World Health Assembly in Geneva in May of this year. If Brazil is forced to change its domestic policies, the current worldwide movement to make medicines more affordable and more accessible in developing countries could be slowed, according to Oxfam.

By opening a formal dispute at the WTO, the United States Government is also sending a strong signal that it will act decisively to ensure high levels of intellectual-property (IP) protection throughout the developing world, whether for pharmaceuticals and other industrial products, or in sectors such as software. The message is particularly directed at larger developing countries with significant industrial capacity, notably Argentina and India, both of which are currently drafting new IP laws.

## Drug firms pressuring Brazil

The dispute between the drug companies and Brazil is currently focused on the price of 2 of the 12 antiretroviral medicines needed by Brazil for effective treatment of HIV/AIDS. The two ARVs, efavirenz and nelfinavir, are expensive, consuming a third of the country's ARV budget. The two drugs are under patent in Brazil, and therefore they cannot be copied by local manufacturers or imported from generic suppliers. After lengthy negotiation, in March 2001 Brazil reached an agreement on price with one of the patent holders, the United States-based pharmaceutical firm, Merck & Co. Brazil is continuing its talks with Hoffman-La Roche, a Swiss firm that has exclusive rights to market nelfinavir in Brazil under an agreement with Pfizer, the United States patent holder. In both cases, the Brazilian Government has warned the companies that if they do not bring their prices down to affordable levels, it will override the "market exclusivity" rights conferred by the patents, and authorize local production by Far-Manguinhos, the Government's Institute of Pharmaceutical Technology. That Institute now manufactures 40% of the locally made ARVs. This procedure, known as "compulsory licensing," does not rescind the patent and, under WTO patent rules, requires payment of royalties to the patent holder. In order to be prepared for production, Far-Manguinhos has imported the necessary raw materials for testing and research from India. In March 2001 Merck wrote to Brazil and said the company believed that Far-Manguinhos was thereby infringing on its patent rights. The Ministry of Health denied this allegation, and the matter remains unresolved.

Foreign pharmaceutical firms have been involved in disputes with the Government of Brazil over the country's medicines policy and patent regime for more than a decade. The companies have used the threat of disinvestment to influence Brazil's health policies, and the firms have also tried to encourage the United States Government, through the Office of the United States Trade Representative (USTR), to apply trade sanctions against Brazil.

## **United States Government complaint against Brazil at the World Trade Organization**

The formal dispute process that the United States initiated at the WTO earlier this year focuses on aspects of Brazil's 1996 Industrial Property Law. If the United States Government wins the case, Brazil must either amend the law or face additional tariffs on its exports to the United States. In addition, all the 140 countries that belong to the WTO would have to ensure that their own legislation is consistent with the ruling.

Brazilian law permits the Government to require a company in any industry to manufacture a patented product inside the country within 3 years of patent approval. If the patent holder does not meet this requirement, the Government may override the patent and either permit manufacturing by a third-party manufacturer or liberalize the import of the patented product from the cheapest international source, without the patent holder's consent.

This legislation could be used to encourage drug companies to produce essential medicines inside Brazil. This could cut Brazil's foreign-exchange expenses and also stimulate the development of the domestic pharmaceutical industry. The legislation can also be used to pressure companies to reduce the cost of imported medicines. The United States claims that the law discriminates against imported products and therefore infringes WTO patent rules known as the Agreement on Trade-Related Aspects of International Property Rights (TRIPS). The Brazilian Government contends that the United States is disregarding the fact that Brazil's provision for local manufacture of a patented product is a safeguard that can be invoked only in a case of "abuse of rights or economic power" by a patent holder, and therefore the provision does not conflict with TRIPS.

Political, economic, and legal pressure from the United States Government over Brazil's IP rules is not unprecedented. The subject has been a source of tension since the 1980s, and on several occasions the USTR has threatened or applied unilateral trade sanctions on Brazil. The USTR has exerted similar pressure on other countries, such as Thailand and the Dominican Republic, in disagreements concerning pharmaceutical products. The United States' principal weapon has been the "Special 301" provision of the country's Trade Act, which allows the United States to impose tariffs unilaterally on a country's exports to the United States if adequate IP standards are not met. In response to domestic public protest over the United States role in the South Africa medicines dispute, the United States Government has said it will exercise restraint in the use of the Special 301 provision in cases that involve vital pharmaceuticals.

However, Brazil is still on the Special 301 "watch list," indicating the United States Government's ongoing concern with Brazil's patent law.

## **Brazil's medicines policy and its HIV/AIDS program**

Brazil's success in dealing with HIV/AIDS is due to a variety of factors. One has been an intense effort in education and prevention, much of it carried out by voluntary groups, activists, and non-governmental organizations. At least one study has indicated that young people in Brazil are possibly the best informed about HIV/AIDS in the world.

Another important factor in reducing HIV/AIDS transmission, morbidity, and death in Brazil has been the free distribution of ARVs since 1996, including those needed to stop mother-to-child transmission. Currently, the country's health service provides free ARV treatment to some 95 000 individuals. One reason this is possible is that 10 of the 12 drugs needed are not patented in Brazil and can therefore be produced as generics, without paying the royalties or high prices that have to be paid in wealthier countries. In 1997 Brazil was spending around US\$ 8 000 per patient per year for ARVs. By increasing generic production, those costs have fallen to just over US\$ 3 000. In contrast, per-patient ARV costs in the United States are around US\$ 10 000 annually.

Brazil is able to produce or import low-cost generic versions of some drugs because the country did not adopt pharmaceutical patenting until 1996. Brazil could thus legally produce equivalents of expensive medicines that had been patented before that date in the industrialized countries, or import them from India, which also did not have patenting on pharmaceutical products. From 1996 onwards, however, Brazil has not had the option of local generic production of new drugs for HIV/AIDS or for any other disease. Without reforms in the WTO's TRIPS regulations, the only way that Brazil can ensure that new drugs are affordable is by price controls, with compulsory licensing as a bargaining chip and as a last resort. This is the policy that Brazil has pursued and that helped the Government of Brazil earlier this year to persuade Merck & Co. to reduce the cost of the HIV/AIDS drugs it sells in Brazil.

## **THE WORLD TRADE ORGANIZATION CASE**

In January of this year the United States requested a WTO dispute settlement panel to resolve its differences with Brazil over its 1996 Industrial

Property Law. The United States Government claims that Article 68 of the Brazilian law violates the WTO TRIPS Agreement. Article 68 stipulates that if a patent holder fails to manufacture a patented product in Brazil within 3 years of patent registration (either in its own factory or by granting a license to a local firm), the Government may suspend the patented product's right to "market exclusivity" and may authorize another company to manufacture it. Since the authorization can be issued without the consent of the patent holder, it is known as a "compulsory license."

In essence, United States trade officials are saying this "local working" requirement discriminates against imported products. For their part, the Brazilians claim this provision is intended to deal with "abuse of rights or economic power" by the patent holder, and therefore complies with TRIPS.

Many complex legal arguments can be made over Article 68 of the Brazilian law, because the wording is not clear. Moreover, since it has never been employed, there is no legal precedent to guide interpretation. In addition, since TRIPS is more akin to a constitution than a patent law, it is itself open to widely different interpretations.

While the two sides have not yet presented their submissions to the WTO dispute settlement panel, the general direction of their legal arguments is clear. The United States Government alleges that Brazil's "local working" requirement unfairly discriminates between locally made and imported products.

For its part, the Brazilian Government argues that the local working requirement is TRIPS-compliant, since it is not a blanket, mandatory measure, and may be imposed only when a specific patent-holding company has abused its rights or economic power. TRIPS does allow for patent rights to be overridden in cases of anticompetitive practice, and the United States Government has itself forced companies to surrender patents in antitrust actions. Thus some of the discussion in the WTO panel hearings may center on what constitutes "abuse." For example, the Brazilians could argue that setting high prices or refusing to transfer technology and expertise through local production could be considered abuse.

### Parallel imports

The United States also objects to the clause in Article 68 of the Brazilian law that states that if a patent holder does not manufacture the patented product in-country, the Government may allow the import of the patented product from the cheapest

source, in a practice known as "parallel importing." Thus if an international drug company imports a patented medicine into Brazil at US\$ 2.00 a dose, the Government could authorize the parallel import of the same medicine from another country where it is priced at US\$ 1.50. However, if the company manufactures the drug locally, the firm is protected from parallel importing, and is therefore freer to set the price according to local market conditions. The United States Government argues that linking this protection from parallel imports to "local working" is a violation of TRIPS. Brazil counters that the parallel importing provision is also a safeguard, to be used in cases of abuse of power.

### Brazil's procedural defense

In its defense submission to the panel, Brazil may also use a more procedural argument, based on the practice of WTO panels to date. Article 68 of Brazil's patent law does not *mandate* TRIPS-inconsistent behavior by the Government, even if it might possibly *permit* it. Brazil can claim that the case is outside the jurisdiction of the WTO unless the Government were to *implement* the law in a TRIPS-inconsistent way, which has not happened to date.

### The WTO dispute settlement process

The WTO will shortly name a panel to hear the arguments in the complaint that the United States has filed against Brazil. The panel's decision will probably be handed down before the end of 2001. If the complaint is upheld, the panel will instruct Brazil on how to amend its law. If Brazil does not do so, the panel can authorize the United States to apply trade sanctions on Brazil's exports to the United States, up to a set value. Either party can also appeal the panel decision to a WTO appellate body.

The final WTO verdict becomes the definitive interpretation of the given WTO rule, and the decision will be applicable in all the countries that belong to WTO.

### ADDITIONAL DRUG COMPANY PRESSURE ON BRAZIL'S PATENT LAW

The Pharmaceutical Research and Manufacturers of America (PhRMA), an industry association that represents the leading research-based pharmaceutical and biotechnology companies in the United States, helped persuade the United States Government to file the complaint against

Brazil with the WTO. PhRMA has also pushed the United States Government to use bilateral negotiations to maintain pressure on Brazil as well as to keep Brazil on the USTR's Special 301 watch list. Apart from the issues that the United States Government will present to the WTO panel, PhRMA objects to a decree on compulsory licensing issued by Brazil's President in October 1999 that regulates Article 71 of the patent law. As does Article 68, Article 71 of the law enables the Brazilian Government to override the market exclusivity conferred by a patent and authorize third-party production of the patented product. Article 71, however, allows for this on grounds of public interest or national emergency, rather than "abuse of rights," and is not concerned with "local working" per se. The definition of "public interest" includes matters important to public health and to social and economic development. If it were to lose this safeguard, the Government of Brazil would be less able to negotiate affordable prices with pharmaceutical firms, leaving the companies freer to charge what they want for drugs, or even to refuse to supply a market. In addition, PhRMA claims that the 1999 decision by the Government to involve the health authorities in pharmaceutical patent approvals could be a violation of the TRIPS Agreement.

Another charge that PhRMA makes is that Brazil is not compliant with the "data exclusivity" provisions of TRIPS. "Data exclusivity" refers to the legal restrictions on access to clinical test data presented to regulatory authorities by a patent-holding company seeking approval for a new drug. This form of intellectual property keeps competitors out of the market and helps maintain high prices for a longer period. Competitors have to replicate trials, at great expense, or wait until the "exclusivity" expires. In some countries even government authorities cannot use an originator's data to assess an equivalent product made by another company, thus further postponing competition. The "exclusivity" term lasts up to 10 years in Europe, and can extend several years beyond the product patent. TRIPS requires that national law protect data against unfair commercial use by third parties, but the large pharmaceutical firms argue that this mandates the introduction of European-style provisions everywhere. This interpretation is hotly contested by manufacturers of generic pharmaceutical products.

## THE IMPORTANCE OF THE BRAZIL SITUATION

According to the Oxfam report, if the arguments of the United States Government and of the

pharmaceutical companies prevail, Brazil's ability to provide affordable medications for HIV/AIDS and other illnesses will be endangered, and WTO rules would prevent Brazil and any other developing country from insisting that patented products be produced locally. If Brazil is also prevented from allowing parallel imports in cases where there is no local production, the prices of medicines will be kept high. With the loss of both of these policy options, the Ministry of Health of Brazil would be in a much weaker position to negotiate affordable prices with major drug companies. If PhRMA succeeds in obtaining the additional policy reforms that it seeks, the control of new medicines will be largely in the hands of a small number of international drug firms, greatly reducing the ability of the Government of Brazil to manage its medicines policy.

If Brazil successfully resists the pressure from the United States Government and the pharmaceutical companies, that could serve as an example for the rest of the world, according to the Oxfam report, much as was true with the recently decided court case in South Africa.

The report on Brazil was prepared by Oxfam as part of the organization's "Cut the Cost" campaign on the prices of medicines. Issued first in English, the report is expected to soon also be available in Portuguese and Spanish. A copy of the full report and other material from that campaign can be viewed on the Oxfam GB Web site, at: <http://www.oxfam.org.uk>.

**NOTE TO READERS:** With this issue of access to affordable medicines, as with any other subject covered in the *Revista Panamericana de Salud Pública/Pan American Journal of Public Health*, expressions of opinions or alternative views are welcomed. Already scheduled for the next issue of the *Revista/Journal* is a piece in which the Pharmaceutical Research and Manufacturers of America will present its point of view.

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## SINOPSIS

### El Brasil lucha por conseguir medicamentos contra el VIH y el sida a precios afrontables

*El acceso que tienen los brasileños a los medicamentos esenciales contra el VIH y el sida y otras enfermedades se ve amenazado por las acciones de las compañías farmacéuticas internacionales y por el Gobierno de Estados Unidos de América, según explica un informe reciente de la Oxfam, organización promotora internacional que ha fijado su atención en el problema de los precios de los medicamentos en*

países en desarrollo. El informe de la Oxfam indica que las grandes compañías farmacéuticas, con el respaldo del Gobierno estadounidense, buscan que el Brasil se vea obligado a comprarles medicamentos patentados muy costosos, en lugar de elaborar fármacos genéricos más baratos dentro del país o de adquirirlos de otros países, como la India. Además, el informe señala que las compañías farmacéuticas se resisten a fijar un techo al costo de sus medicamentos, como quisiera el Gobierno del Brasil. Gran parte del desacuerdo se centra en torno a la Ley de la Propiedad Industrial que entró en vigor en el Brasil en 1996. Tanto el Gobierno de Estados Unidos como las grandes compañías farmacéuticas sostienen que ciertas provisiones de esa ley violan el

Acuerdo sobre los Aspectos Comerciales Internacionales de los Derechos de Propiedad Intelectual de la Organización Mundial del Comercio (OMC). El Gobierno de Estados Unidos le ha pedido a la OMC que convoque un panel de debate para escuchar los argumentos a favor y en contra de la ley brasileña. Si el Gobierno estadounidense gana la partida, el Brasil tendrá que enmendar la ley o enfrentar tarifas adicionales sobre los productos que exporta a Estados Unidos. Además, los 140 países que pertenecen a la OMC tendrán que cerciorarse de que sus propias leyes sean compatibles con el dictamen de la OMC.

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### Call for Conference Presentation Abstracts

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*Subject:* Global Health in Times of Crisis  
*Deadline for submissions:* 8 October 2001

An increasing number of crises are harming the health of families and communities around the world. Military and political conflicts, natural disasters, environmental catastrophes, and collapsing economies result in injuries and death, psychosocial trauma, rapid spread of communicable diseases, food insecurity, nutritional deficiencies, sexual abuses, and the breakdown of health services.

Given this reality, the Global Health Council (GHC) is inviting abstracts for proposed presentations at its 2002 Annual Conference, which will have the theme of "Global Health in Times of Crisis." The conference will take place in Washington, D.C., 28–31 May 2002. Based in the United States of America, the Global Health Council is a large membership alliance dedicated to improving health worldwide.

Presentations at the GHC conference must impart research and experience related to the issue of health in times of crisis. The presentations must fall into one of the following conference tracks: health, human rights, and advocacy; disasters and conflict; issues in transitioning from disaster to development; infectious diseases and epidemics; urbanization and socioeconomic change; environmental threats to health; health policy and financing; and health service delivery and behavior change. Presentations at the GHC conference can be made in the form of panel sessions, roundtable sessions, or poster sessions.

*Information:*

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