

# Brazil's Generic Drug Manufacturing Success and the policies that permitted it

*Over 500,000 Brazilians are either HIV-positive or suffer from AIDS.*

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## ***Brazil's Economic Status***

Brazil is a country that has undergone many political and economic difficulties. Because of this it has not been able to grow and develop economically as many other countries around the world. With time, new political powers that have done considerable efforts to improve its economy have emerged. As of today, Brazil's economy prevails over that of all other South American countries. However, its foreign debt has not reduced enough as to see a considerable constant economic growth reflected by the strengthening of exportation. This implies that even though the economic picture of Brazil has increased in the past years, it still has a long way before it is considered a competent economic power at worldwide level.

Currently, Brazil's most significant economic source is in the industrial and manufacturing sector. However, in the past few years, pharmaceuticals have caused a positive impact on the economy. Brazil is the 11<sup>th</sup> largest pharmaceutical market in the world in sales and the 6<sup>th</sup> in volume. It has the leading role in South America's pharmaceuticals and most large international pharmaceuticals, like Novartis, Roche and GSK have their main production and supply bases in South America established in Brazil. More than 300 companies, including subsidiaries of most major multinational laboratories and local pharmaceuticals, compose this industry (*UK Trade and Investment*).

## ***The need for a reform of the Patent Laws***

The growth of this market is mainly due to a new Intellectual Property Law enacted in 1996. This law provided a 20-year patent for drugs, including protection for those not yet on the market. This law was first enacted in order to reduce patent piracy in Brazil. In 1995, the U.S. industry's losses in Brazil due to patent piracy were \$720 million. Because of this, the U.S. Trade Representative put Brazil under watch and threatened with commercial sanctions if nothing was done about this. Brazil also realized that by granting pharmaceutical patents and reducing drug piracy, the cost of medicines would decrease, making indispensable drugs affordable to poor citizens. Brazil also realized that granting patents for drugs would be an incentive for scientists and companies to research in this area and improve not only the cost of living of the country by producing drugs locally, but also the economy, unemployment, and public health of the country. This would be due to the fact that with these incentives large international pharmaceuticals would be interested in establishing plants in Brazil. These new patent laws in Brazil pleased most countries since this would attract more R&D in the pharmaceutical field, which would help improve public health at a global level (USDOS).

## ***Current Pharmaceutical Market***

The potential for pharmaceutical market is substantial. Currently only 30% of the population has access to medicine regularly, so the actual medicine profits are low. Health insurance does not cover medicines, but the government provides treatment to special chronicle diseases, such as AIDS and diabetes. The government is aware of this problem and is seeking for solutions that will allow more access to a wide variety of medicines. Brazil is the leader in life-style drugs, such as vitamins (*UK Trade and Investment*).

The largest pharmaceutical market is that of generic drugs. Brazilian government realized that in order to be able to provide better access to medicines, they would need to recur to generic drugs. After this introduction, the prices of drugs have decreased considerably and the market keeps increasing in such a way that today it constitutes 5% of the market volume. However, recent studies show that most drugs are still restricted to high-class population. The government continues to encourage generic drugs industries to reside in Brazil since they believe that with these drugs, eventually the low-income population will have easy access to most drugs. In order to encourage drug companies in Brazil, the government offered preferential purchase options and special financial investment conditions to pharmaceuticals that establish plants in the country.

Currently, manufacturing under a license is the best way to develop business in patented or generic drugs in Brazil. They comprise a large

pharmaceutical industry with high quality manufacturing, sales and distribution that is ready to include more products and world-known pharmaceuticals.

### ***How has Brazil become a dominant figure in generic drug manufacturing?***

The success of Brazil's generic drug manufacturing originates from the freedom of the World Trade Organization's (WTO) policies and also its laissez-faire attitude concerning intellectual property rights of both Brazilian and international issues. The policies prior to 2003 allowed developing countries to manufacture their own generic drugs if name-brand drugs were too expensive. Many developing countries lacked the resources to manufacture generics, but Brazil's generic drug base had been growing since the 70s.

One of the major generic drug manufacturers, Laboratoria Cristalia, was started in 1972 by "Dr. Ogari de Castro Pacheco to make cheaper drugs for patients with mental illnesses at his private clinic next to the drug lab," (Bloomberg). The laboratory now employs 1.200 workers and manufactures 150 drugs.

Both Brazilian companies and international companies have fueled Brazilian generic drug manufacturing. A joint venture between Teva of Israel and Laboratorios Biosintetica formed in November 2000 (Rich, Para. 5) to take advantage of the infant generic market in Brazil. The new

company, BioTeva planned to introduce a total of 50 generic products into the market by the end of 2001.

### ***What was the role of the WTO?***

Africa was facing a health crisis from AIDS and appealed to the WTO to allow the sale of generic pharmaceuticals to developing countries. Africa wanted to buy generic AIDS drugs from countries like India and Brazil who had an established generic drug-manufacturing base. The WTO is composed of 146 member countries and entered into a deliberation process among all the countries to determine the viability of allowing Brazilian made generics to be sold in Africa. The deliberations took over eight months to come to a consensus. The United States had been trying to protect the interests of drug companies because it thought pharmaceutical companies would lose control of their patents. The final breakthrough occurred when African country representatives pleaded to the WTO that “nearly 2.2 million Africans have died from AIDS and other killer diseases since the issue became deadlocked on Dec. 16 [2002],” (Cheap drugs, Para. 3). Brazilians benefited from the cheaper generics because Brazil had the capacity to produce them. Africans died because their country lacked the capacity to produce generics. Members of the WTO finally realized the

gravity of the situation and allowed developing countries to purchase generics from Brazil and India.

When selling generic drugs to a developing country, the WTO must be notified and the drug maker must obtain an export license from its government (Bloomberg, Para. 12).

### ***How the Brazilian government negotiated with pharmaceutical companies***

Shortly before the August 2003 decision to allow Brazil to export generics to countries like Africa, Brazil set a deadline with Merck, Pfizer, and other companies to reduce the cost of AIDS drugs (Bloomberg, Para. 1). The Brazilian drug market, especially AIDS drugs, is important to these drug companies because Brazil ranked sixth in medicine consumption in 2000 (Rich, Para. 10). Brazil presented an unprecedented and unique case because its capacity to produce generic drugs surpassed any other countries ability. In addition to the Brazilians' ability to produce generics, their intellectual property policy contained a 1997 law that voided patents if companies employed price abuse (Clendenning, Para. 3). The pharmaceutical companies faced losing significant profits in the Brazilian market and jeopardizing their patents or reduce the AIDS drugs price.

Brazil took its first steps in breaking AIDS drugs patents in early September 2003. Brazil requested reductions of up to 50 percent on three

different AIDS drugs. Brazilian officials claimed to have reverse-engineered the three drugs involved in the negotiations, and they would not be able to produce the drugs in sufficient quantities quickly enough (Miriam, Para. 12). Brazil finally negotiated the prices of the AIDS drugs to a satisfactory price, and won a huge battle against the pharmaceutical companies.

Despite winning a drastic reduction in AIDS drugs pricing, Brazil chose to begin manufacturing generics of the medication due to rising costs. Brazil's announcement in late November 2004 brought more attention to an already famous program. Brazil gives out the medication free of charge to patients, and the demand continued to increase. The long-term viability the anti-AIDS program was in danger, and this time, pharmaceutical price reduction could not solve the problem. Brazil's head of AIDS Programme, Pedro Chequer said it was the only way Brazil could afford to keep up its anti-AIDS strategy. Brazil requested voluntary licensing from the pharmaceutical companies, but was prepared to break the patents using compulsory licensing (Osava, Para. 21). Merck announced in December that it would allow Brazil to make one of its AIDS drugs because a further reduction in price would result in an unprofitable drug for Merck.

Brazil has managed to fuel a vibrant generic drug manufacturing industry and also attract cutting-edge biomedical industry based on

unstable property rights. Ireland and Singapore offer appealing tax structures, but have failed to produce innovative pharmaceutical sectors. Innovative products are not typically developed in countries without reliable property rights (O'Grady, Para. 25). Brazil is an exception but continues to be pressured by the United States to tighten its property rights to protect U.S. pharmaceutical companies. Brazil claims that tightening property rights will result in an erosion of the anti-AIDS programs it has fought so hard to maintain.

In short, Brazil's ability to negotiate the prices of AIDS drugs represents a market failure, namely in terms of intellectual property rights. Brazil can only hold on to its poor-country status for so long. Its spending has increased and its poor government and educational infrastructure largely contribute to its poverty. Brazil cannot continue to claim a health crisis in order to void other country's patents and produce generics. It also cannot continue the practice of voiding a country's patent based on price gouging. Brazil decides what is price gouging and of course it will be subjective. Brazil needs to overhaul its educational infrastructure and property rights to reflect the views of respected countries.

## ***Brazil's Generic Drug Manufacturing Success and the policies that permitted it***

Brazil's capability of producing generic drugs has caused many disputes between Brazil and the United States patent holders, where the production and distribution of generic drugs for human immunodeficiency virus/acquired immune deficiency syndrome (HIV/AIDS) has been leading the controversies for the past few years. In order to justify breaking the patents for some of the drugs needed in their AIDS drug cocktails, Brazil declared AIDS a national emergency. Brazil has the largest number of people infected with HIV in Latin America and the Caribbean. In some regions, this disease means losing basic rights, both in health care and society, and facing a discriminating and stigmatizing community. In a larger scale, without the proper medical treatment, AIDS would prevent hundreds of thousands of people from being able to provide for their families, as well as eliminate generations of food producers in some countries, increasing the number of people living in hunger. By having the state provide antiretroviral treatment, Brazil managed to reduce the number of deaths caused by AIDS by more than 50% since 1996. In this time period it has also reduced the number of people that need to be hospitalized because of the disease by 80%. The large scale in which these antiretroviral treatments have been implemented has only been possible because of the large reduction in the price of the AIDS drugs. These drugs do not cure the fatal disease, but it allows those infected to live a longer life and gives

them the strength to be able to provide for their families in a way where the disease is not as recognizable and thus the negative societal impact is also diminished. Though much of the reduction in price was achieved by having the Brazilian government negotiate with the companies that produce the patented drug, a considerable reduction in the price can be attributed to the production of the generic equivalent of the drugs with the highest prices.

### ***Brazil's Patent Laws***

This mass production of AIDS drugs in Brazil has only been possible because of Brazil's patent laws and the World Trade Organization's (WTO) Trade Related Aspects of Intellectual Property Agreement (TRIPS) as well as the Doha Declaration, which reaffirmed the purpose of TRIPS. The easiest way for Brazil to produce generic drugs would be by following Article 68 of their 1997 patent law, which requires a foreign company to begin production of the patented product in Brazil within three years of obtaining the patent. The US has filed complaints against this law, suggesting it is discriminating against imported products, yet Brazil holds that Article 68 is only enforced when the drug companies abuse the economic power associated with holding the patent. In this manner, if the companies that hold the patents for expensive AIDS drugs do not begin production in Brazil within the specified time period, they hold no legal right to prohibit the generic production of the drug. The ideal solution to this problem would have the Brazilian government and the pharmaceutical companies agree on a price for the

drug in question. Though this solution has ended Brazil's threats to produce the generic version of certain drugs, the lack of a 100% success rate has been the cause of the controversy.

### ***TRIPS and the Doha Declaration***

When companies that hold the drugs patents and the Brazilian government cannot agree on setting a price for the drug, the government has often resorted to the rights involved with TRIPS and the Doha Declaration. TRIPS protects the companies that develop and patent the drugs by granting them twenty years of exclusivity in producing the drug. With this protection, for a country to begin producing generic drugs before the twenty-year term is over, it must obtain consent from the company. However, TRIPS also provides countries to bypass this patent in certain ways such as compulsory licensing and exclusions on patent admissibility for some products, subject to the payment of royalties. Compulsory licensing does not require the country to obtain the patent holder's permission before beginning to produce the equivalent generic drug, and can only be carried out when facing a national emergency. Brazil declared the AIDS outbreak and epidemic to be such an emergency and was able to take advantage of TRIPS for reducing the price of the AIDS drugs. In June 2001, in a TRIPS Council meeting, the contents of the agreement were discussed since some African countries felt

that the full patent protection should not apply to countries that can afford the drugs in cases of national health emergencies. They felt that the duration of the patent protection and the degree to which the patent could not be infringed should be revised for low-income countries, but this change would not apply to countries that are economically capable of obtaining the patented drug. From this discussion the Declaration on the TRIPS Agreement and Public Health (the Doha Declaration) was developed in November 2001. The Doha Declaration reaffirms the rights of the countries suffering health emergencies and reestablishes the purpose of TRIPS as that of public health interest. Many countries including the United States agreed this declaration on.

Article 5 of the Doha Declaration describes the relationship between countries regarding the patented products. Article 5a establishes that each provision of TRIPS has to be interpreted individually, taking into consideration the overall objective. Article 5b provides the countries with the rights of granting compulsory licenses and establishing the rules for granting them. Article 5c allows the countries to decide what can be considered a national emergency, in which case a government can issue a compulsory license without having contacted the patent holder. Article 5d states that TRIPS does not allow patent protection for secondary sales of the product, and each country decides to what extent the patent will be valid after the initial sale of the product. In this manner, each country decides if it will allow parallel imports such that the products can possibly be bought outside the country borders for a cheaper price and reintroduced into the

country for redistribution. Since the member countries agreed the scale of the HIV infection in Brazil was a national health emergency, in compliance with Article 5b of the Doha Declaration, Brazil is able to use compulsory licensing when necessary for its AIDS drugs.

### ***AIDS drugs accessible for all***

In 2001, the United Nations Commission on Human Rights voted almost unanimously in favor of making accessibility to AIDS drugs a human right. The only opposing vote was that of the United States. The reasons for this action would have to be further studied to find the justification. This act could possibly be attributed to AIDS not being as major an issue in the US, or because most of the companies that hold patents for AIDS drugs, which would be the ones affected by this act, are US pharmaceutical companies. However, the US government and the pharmaceutical companies are two different entities, and though they might be in agreement with not allowing AIDS drugs to be a human right, the US government is not against the Doha Declaration. When faced with the possibility of an anthrax epidemic, the US threatened to use compulsory licensing to obtain a lower price for the antibiotic that could cure this disease. Though the action was not carried through, the intention of making use of Article 5b of the Doha Declaration shows the government recognizes any country can suffer a national health emergency and ways to avoid patents in this situation are necessary. In this

manner, possible solutions to the problem between Brazil and the pharmaceutical companies cannot regard a change in the Doha Declaration or a direct intervention between the US government and Brazil's use of compulsory licensing. Since all other members of the UNCHR recognize AIDS drugs should be a human right, the extent of the AIDS infections in Brazil provide a real and solvable problem, so a finer definition of a 'national health emergency' would not be able to solve the patent conflict. Thus a solution must be devised in some other way.

### ***United States' position on the Doha Declaration***

United States pharmaceutical companies, the major provider of foreign drugs in Brazil, are not in agreement with the Doha Declaration since they lose profit whenever compulsory licensing occurs. Their major argument up to date is that by allowing compulsory licensing, which will mostly take place in developing countries; the pharmaceutical companies will not be motivated to continue their research and development of drugs that would mostly be used in these countries. However, large pharmaceutical companies have admitted both that they spend more than twice as much on marketing than on research and development, and that they could sell AIDS drugs for a 90% discount and still make a profit. By taking these facts into consideration, possible solutions for the compulsory licensing issue can be established. The problem being that pharmaceutical companies do not want to waste their resources on drugs that will bring a smaller, but existing,

profit, a possible solution would be to require large enough companies to produce a certain amount of drugs that will help control diseases in developing countries, where 'large enough' would be determined by their resources, facilities, and annual profit. Since the governments would most likely buy these drugs, no money has to be spent on big advertising campaigns. To ensure continuous research, a percentage of the research and development budget would have to be dedicated to drugs for major diseases in developing countries even if the disease is not common in the US. By describing everything in percentages, the amount of money and such will be determined by the magnitude of the company. Other countries with major pharmaceutical companies should also adopt this regulation.

### ***Compulsory Licensing and AIDS drugs***

Pharmaceutical companies that hold the patents to the AIDS drugs in a certain country have been further affected by compulsory licensing since 2003. In a WTO meeting, compulsory licensing was extended to permit countries to import generic drugs from other countries in the case of a national health emergency without having to consult the rightful patent owner. However, this importation of generic drugs can only be carried out if the country itself is not capable of producing the generic drugs. Brazil benefited from this addition to the compulsory licensing definition since it began importing generic drugs from countries that do not yet have to comply with the international patent. Even though Brazil has a

developed pharmaceutical industry and they are capable of producing the generic drugs, they benefit from compulsory licensing since they cannot produce the AIDS drugs quickly enough to account for the importing costs of the patented drugs for the antiretroviral drug program. Therefore, pharmaceutical companies should be more motivated to reach agreements on the price of the AIDS drugs, since it is now easier for the country to receive the drugs from elsewhere. Otherwise, the companies should allow for the production in Brazil such as the agreement with Merck for the Efavirenz and Indinavir drugs, since the company will still receive royalties. Regarding importation from other countries, there could be an amendment to the international patent laws such that the patent is enforced in all countries at the same time. In this case, the first international patent that is recognized would provide the date of effectiveness of the international patents in the other countries. However, this would involve a certain alliance between all countries that might not be feasible.

### ***Solutions to Brazil's AIDS drug problem***

A possible solution to the Brazil AIDS drug problem can be an agreement similar to the one in 2002 between Brazil and Medecins Sans Frontieres (MSF) in South Africa. The agreement is such that MSF purchases AIDS drugs from FarManguinhos, a Brazilian pharmaceutical company, and this money has to go directly into research and development for AIDS drugs and drugs for other

neglected diseases. By buying from the Brazilian company, MSF pays only half of what it would have paid if bought the US patented drugs. This program could also be implemented between the US, Switzerland, and any other country with pharmaceutical companies that provide AIDS drugs to Brazil, such that Brazil will accept a higher price than desired in the negotiations with the pharmaceutical companies, but the payment has to go directly into the research and development for drugs that cure or control diseases in developing countries. The agreement would have to be drawn out such that the whole payment, not just the net profits, would go into research. This way, the morals of the countries are not compromised and both countries would be helping in the advance of solutions for less studied diseases.

If pharmaceutical companies do not want countries such as Brazil to use compulsory licensing as an option for AIDS drugs, then an agreement must be reached between the government and the pharmaceutical company. However, other measures can be taken such that the pharmaceutical company that had its patent waived can profit more from the production of the generic drugs. First of all, parallel importing should affect the result of the agreement. If parallel importing is allowed in the country and the country can benefit from it, the price the pharmaceutical company proposes should decrease, especially since access to these drugs is now a human right. Also, the conditions by which parallel importing and cross-border trading are allowed should be defined more clearly and a tax or some other measure could be established such that it does not affect the

pharmaceutical companies as much, but the people obtaining the drugs can get the lower price for the drug. However, this tax measure does not influence Brazil since the antiretroviral treatment is provided free of charge.

The most effective yet feasible solution to Brazil's problem would then be the one previously mentioned relating the relationship between Brazil and MSF. If a price agreement cannot be reached, and the pharmaceutical company has made it clear they do not wish Brazil take compulsory licensing as a course of action, then a lower price can be established such that Brazil buys the drug and the capital goes into research and development for drugs that treat diseases that mainly affect developing countries. Brazil has been recognized as having an effective fight against AIDS, and other countries strive to be the same way. Sub-Saharan countries can base most of their help from the US since the US provides special help to those countries. However, as long as the government can keep providing, at least to an acceptable degree, and the pharmaceutical companies are still making profit and keep researching AIDS, an agreement can be reached and the country will not have to use compulsory licensing.

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