IV. CHAPTER. ANALYZING THE BRAZIL CASE

A. General Overview: Brazilian statistics and the public healthcare system

Brazil is the fifth largest country in the world both in geographical area and population. The country is 8.5 million square kilometers and had 194.9 million people in 2010. It is growing at a 1% rate[600] and reached more than 199 million people in July 2012.[601] The country's nominal gross domestic product (GDP) at US$2.476 billion made it the sixth largest economy in the world in 2011.[602] Brazil economy is characterized by large and well-developed agricultural, mining, manufacturing and service sectors, as well as a large labor pool. With a GDP per capita of US $12,594 in 2011,[603] the World Bank classifies Brazil as an upper middle level country.[604]

As one of the BRICS countries, Brazil's booming economy has gone into overdrive with biofuels and deep-water oil reserves, providing energy independence, expanding the country's presence in international financial and commodities markets, and increasing exports of aircraft, electrical equipment, automobiles, ethanol, textiles, footwear, iron ore, steel, coffee, orange juice, soybeans, corn and beef[605] After becoming a net external creditor in 2008, the country was hit by the global financial crisis the following year. Nevertheless, Brazil was the first emerging market to recover from the crisis and experienced a 7.5% growth rate in July 2010, the highest rate in the past twenty-five years, leading the government to take measures to cool down the economy in response to rising inflation.[606] The country's expected rate of growth for 2013 was 4%.[607] Agriculture and related sectors like forestry, logging and fishing accounted for 5.5% of

600 See *World Bank*, Brazil's Profile, lines 1-2.
601 See *CIA*, Brazil, item 3.
602 See *World Bank*, Gross Domestic Product 2011, line 6.
603 See *World Bank*, GDP per capita, line 27.
604 See *World Bank*, Brazil's Data, table 1.
605 See *The Economist*, The Economy of Heat, table.
606 See *CIA*, Brazil, item 5.
607 See *Banco Central,* Inflation Report, p. 19.

GDP, illustrating the importance of agribusiness in the country's trade balance. 27.5% of GDP was from industrial activity including automobiles, steel, petrochemicals, computers, aircraft, and consumer goods. Services were responsible for 67% of GDP in 2011.[608]

Brazil was placed in eighty-fifth position among the group of developed countries with high human development according to the rank by the Human Development Index published in the United Nations Development Program's Human Development Report released on November 2, 2011.[609] This classification takes into account that public expenditures on education represented 16.8% of total government expenditure in 2009, higher than the US 13.1%.[610] However, health represented 9% of GDP in 2010 similar to the Congo and Sierra Leone, African countries with low human development.[611]

Despite the relatively good classification by the UN Development Program, 21.4% of the Brazilian population still were living below the poverty line in 2009 and illiteracy rates reached 11.4%.[612] This is indicative of the long-existing unequal distribution of wealth in Brazil – one of the worst in the world. In 2008, 24.8 % of the country's workforce had a monthly income per capita below half of the local official minimum wage, which amounted to $410 reais (approximately US$242), whereas the population earning more than $2,050 reais (around US$1,206) corresponds to only 5.5% of Brazilians.[613]

The Brazilian Gini coefficient for income, which measures unequal distribution of family income in a country and ranges worldwide from approximately 23.0 to 70.9 (referring to Sweden and Namibia respectively)[614] was at 51.9 in 2012.[615] The Gini coefficient was only worse for Haiti, Central African Republic, Sierra Leone, Botswana, Lesotho, South Africa and Namibia.[616] In 2008, the index was reduced by 0.505 for Brazil and represented a 7% decrease in income disparities.[617] The improvement

608 See *CIA*, Brazil, item 5.
609 See *UN*, HDI rankings, column 2.
610 See *World Bank*, Spending on Education, line 27.
611 See *World Bank*, Spending on Health, line 27.
612 See *CIA*, Brazil, item 3.
613 See *IBGE*¸ Income Search, p. 192.
614 See *CIA*, Gini Index, lines 87, 116.
615 See *Holanda et al.*, Gini Index, p. 5.
616 See *CIA*, Gini Index, lines 14, 22, 49, 70, 87, 108, 112.
617 See *Schlindwein*, IPEA's measurements of Gini coefficients, p. 48.

may reflect governmental long-term investments in social programs, such as the so called "Bolsa Família" which provides income to poor families and mandates children schooling in exchange,[618] within the context of general economic development.

The United Nations and the World Bank estimate that a quarter of the Brazilian population has no access to drinking water, living in very poor conditions without basic sanitation. Diseases typically found in poor countries, such as tuberculosis and Hansen's disease, still afflict Brazilian people.[619] However, some specific campaigns have proven successful including the eradication of Poliomyelitis since 1994, after nationwide vaccination campaigns organized by the Ministry of Health.[620]

In spite of social and economic inequities, Brazil was the tenth largest market for pharmaceutical products in 2008 and it was expected to be the eighth largest in 2013, representing 2% of the worldwide market.[621] Pharmaceutical industry sales in the country were around US$15.7 billion in 2009.[622]

Brazil's strategic importance in the global pharmaceutical market takes into consideration the publicly funded healthcare system, entitled "Sistema Único de Saúde" (SUS). The system was created through the Federal Constitution of 1988, which mandates the government to provide universal healthcare differing from the previous public system, which only provided healthcare to those who paid social security taxes.[623] However, currently there is a two-tier healthcare system in Brazil. 73.7% of the population depends on the public system to have access to medical treatment, and only 26.3% (around 49.1 million people) are able to afford a private insurance.[624] The SUS is a unified system and encompasses the three levels of government – federal, state and municipal – each with its own attributes, and working in coordination under the national guidelines established by the federal government. The SUS budget is part of the annual social secu-

618 The "Bolsa Família" social program is sponsored by the Brazilian federal government and was created by Law 10836 in 2004, aiming to reduce social inequalities.
619 See *IBGE*, Municipal Social Figures, p. 113, 116.
620 See *Schatzmayr*, Eradication of polyomielitis in Brasil, p. 12.
621 See *Interfarma*, Market Trends; *ABAMEC*, Pharmaceutical Industry Wins Millions, para. 2.
622 See *Interfarma*, Pharmaceutical industry sales in Brazil, table.
623 See *Martins*, Social Security Law, p. 6-15.
624 See *IBGE*¸ Overview of the Brazilian Health Care System, table 11.

rity budget. In 2008, the federal government financed 45.51% of the system, whereas states and municipalities contributed 25.28% and 29.21% of the $110.5 billion reais respectively (around US$53 billion).[625] In the same year, the federal government allocated $54.1 billion reais (around US$26 billion) to health expenses and, in 2009, $59.8 billion reais (around US$30 billion). In 2010, the amount increased to $62.5 billion reais (around US$32 billion), representing 13.7% of the total of $456.7 billion reais for social security.[626] Brazilian healthcare expenditures (7.5% of GDP) are below the world average (9.7%), with an even lower public share (3.6% of GDP), which is inconsistent with a public universal healthcare system.[627]

Public expenditures for medicine represent only 0.33% of GDP, whereas the average for OECD countries amounts to 0.92%.[628] Despite this, 12% of the Ministry of Health budget – $77,1 billion reais in 2011[629] – is allocated to purchase medicine[630] and the total Brazilian drug market amounts to 28 billion reais,[631] and it could reach $87 billion reais in 2017.[632] These absolute figures in economy of scale make the Brazilian market for pharmaceutical products very attractive, possibly one of the most attractive in the world, since the Brazilian government may be deemed one of the biggest individual purchasers.

Public lawsuits have reached the Brazilian Supreme Court that address the extension of the constitutional right to universal healthcare. According to the highest national court, the right to health comprises the right of having government policies to promote and protect health, as well as the right of individual citizen's to request the guarantee of this right before a court.[633] Accordingly, individuals can seek judicial orders to obtain medications from the government, which were not initially supplied by the

625 See *Interfarma*, Health access and funding, p. 7.
626 *Id.*
627 See *Interfarma*, Health access and funding, p. 14-15.
628 See *Interfarma*, Health access and funding, p. 16.
629 See *MoH*, Health budget, para. 1.
630 See *MoH*, Expenditure in medicines, p. 2.
631 See *MoH*, Industrial numbers, line 5.
632 See *Data Mark*, Brazilian Pharmaceutical Industry, para. 2.
633 See *Supreme Court*, AR on Liminar Suspension 47, p. 8-28.

SUS, illustrating further how appealing the Brazilian government is as a large purchaser of pharmaceutical products.[634]

B. AIDS in Brazil

1) Statistics

The first case of AIDS in Brazil was reported in 1980. Data from June, 2011 shows that there are 656,701 registered cases of the illness and the government estimates that there are around 530,000 people living with HIV in the country. From the start of this epidemic until 2011, 253,706 deaths related to the disease have been reported and 38,800 new cases have been identified each year.[635] The growth of the AIDS epidemic is considered stable, with 20.2 cases for each 100,000 inhabitants.[636]

In the period from 2002 to 2011, the rate of AIDS in the Southeast area of the country, where most of the instances are concentrated (58%), dropped from 27.5 to 21 cases for each 100,000 inhabitants. In other regions the rate increased or stabilized. There was a drop from 33.7 to 30.9 in the South and from 18.5 to 17.5 in Central-West, and an increase from 9.3 to 13.9 in the Northeast and from 10.9 to 20.8 in the North. The age group of 20-59 is where most occurrences in both genders are concentrated.[637]

Although it is currently considered stable, the infection rate grew exponentially in Brazil during the 1980s. In 1990, the World Bank predicted there would be 1,200 thousand cases by 2000.[638] The Brazilian Ministry of Health later published numbers that arrived at about half of this prediction.[639] The stabilization of the AIDS epidemic in Brazil was possible only through government policies that have provided universal access to an-

634 *Id.*, p. 23-31; see also *Supreme Court*, AR on STA 361, p. 7-8; *Supreme Court*, AR on STA 328, p. 6-8.
635 See *MoH*, Aids in Brazil, para. 1.
636 *Id.*
637 *Id.*, para. 2.
638 See *World Bank*, AIDS in Brazil result story, para. 1.
639 See *IBS*, fighting AIDS, para. 2.

tiretroviral drugs and prevention campaigns. The UN recognizes Brazil as a model to be followed by developing countries.[640]

Since the mid-1990s, the Brazilian government has granted universal access to antiretroviral treatment for AIDS. This has been the key to success of the Brazilian program against AIDS, which includes other preventive measures such as providing one billion condoms for free.[641] Data from the Ministry of Health reports that between 1997 and 2004, after the introduction of universal access to antiretroviral treatment, which combines drugs with different modes of action, there was a 40% drop in mortality, a 70% drop in morbidity and an 80% drop in hospital admissions.[642] As a result of this successful program, costs of hospital admissions and medical and ambulatory care have been reduced by over US$2.3 billion between 1997 and 2004.[643] These healthcare expenses have been replaced by the cost of the anti-AIDS program at around US$200 million.[644]

Even though the program has been successful, because of the constant but increasing number of patients, the enlarged life expectancy of treated patients, the need to administer second and third generation drugs – which are more expensive and often subject to patent protection – has led to a significant increase in government expenditures. On average there are an estimated 33,000 new diagnosed cases in the country and each year almost 20,000 new patients are incorporated into the program.[645] From 2004 to 2005, expenditures on antiretroviral drugs increased 60%, raising spending by the Ministry of Health from US$250 million to US$490 million, yet the number of patients rose less than 10%.[646]

640 See *The Economist*, Brazil AIDS programme, para. 2; and *World Bank*, AIDS in Brazil result story, para. 3.
641 See *World Bank*, AIDS in Brazil result story, para. 6, item 14.
642 See *MoH*, 2008 Brazilian Health, p. 139.
643 *Id.*
644 See *Teixeira, Vitoria, Barcarolo*, Antiretroviral treatment: the Brazilian experience, para. 9.
645 See *Greco, Simão*, Brazilian policy of universal access to AIDS treatment, p. 37-45.
646 See *MoH*, Antiretroviral drugs expenditure report.

2) The Anti-AIDS Program

After the first diagnosis in the early 1980s, AIDS in Brazil quickly evolved as an epidemic and demanded the attention of government at the national level. In 1986, the Ministry of Health created the National Sexually Transmitted Diseases and AIDS Program, by means of Ordinance 236/1985, and demanded that AIDS be treated as a public health priority. The National Program comprised policies and strategies to prevent and provide assistance in this area under the umbrella of Articles 6 and 196 of the Federal Constitution that guarantee the right to health and that mandate universal healthcare, as well as Law 8080/1990 that regulates government obligations regarding public health.

Despite unorthodox and controversial measures, the Brazilian national program combating HIV and AIDS was able to reach many different groups, including those that represented a high level of transmission. In contrast to many other countries, early on, priority was placed on an aggressive campaign promoting the use of condoms, which included free distribution during the carnival festival. This initiative resulted in an increase from 4% in 1986 to 48% in 1999, and 55% in 2003, of the use of condoms during first sexual encounters.[647] Groups of prostitutes were targeted and received informational material and condoms.[648] The program has included also supply of disposable syringes, resulting in a decrease of HIV infections among users of illicit injected drugs from 52% in 1999 to 41.5% in 2001.[649] One of the program's principal measures, seeking to reduce mortality and enhance the quality of life of patients, is free treatment within the SUS.

Pharmaceutical assistance under the SUS system is provided by Article 6 of Law 8080/1990, which establishes statutory access to medicine. By means of Ordinance 3916/1998, the Ministry of Health approved the National Drug Policy, aiming to guarantee safe, effective and quality drugs at the lowest cost possible, as well as to promote access to essential medicines. The guidelines of the Policy include a) adoption of a list of essential medicines, b) sanitary regulation of drugs, c) broadening the scope of pharmaceutical assistance, d) promotion of rational use of medicines, e) scientific and technological development, f) promotion of drug production,

647 See cited: *Levi*, *Vitória*, Fighting against AIDS, p. 2374.
648 See *Reel*, Where Prostitutes Also Fight AIDS, para. 5-6.
649 See cited: *Levi*, *Vitória*, Fighting against AIDS, p. 2375.

g) guarantee of safety as well as efficacy and quality of drugs, and h) development and enablement of human resources. The Policy must meet constant changes in the Brazilian epidemiological profile, which encompasses diseases typically found in developing countries as well as those often found in developed countries. Adopting a national list indicating what pharmaceutical active ingredients are deemed basic and indispensable for the treatment of a broad spectrum of diseases is important within the context of the National Sexually Transmitted Diseases and AIDS Program. Since antiretroviral drugs are on this list, their acquisition is managed by the federal government by means of the Ministry of Health.

The key to combating mortality and enhancing quality of life of patients is the universal and free distribution of antiretroviral drugs as of the enactment of Law 9313/1996. The statute embodies the National Sexually Transmitted Diseases and AIDS Program and mandates that carriers of HIV and AIDS receive every medication needed for their treatment free of charge through the SUS. The Ministry of Health is responsible for issuing standards indicating the drugs to be used in each stage of the infection and disease, so as to guide the purchase of the medications by the SUS managers.[650] The drugs purchased by the federal government are, then, combined (commonly referred to as the anti-AIDS cocktail) and distributed to patients registered in the program in accordance to the prescribed treatment and they are not sold in pharmacies.[651]

Despite positive results, increasing expenditures for purchasing antiretroviral drugs have posed a threat to the long-term existence of the Brazilian program. From 1996 until 2005, around US$2.5 billion were spent to purchase antiretroviral drugs: six of them, namely, AZT, lamivudina, tenofovir, efavirenz, atazanavir and lopinavir/r, were responsible for the increase of US$284 million in expenditures between 2001 and 2005.[652] In 2005, the National Program's effective expenditure of US$500 million exceeded the expected budget of US$250 million, which already repre-

650 See article 1 of Law 9313/1996.

651 The current drugs used in the program are: Abacavir, Didanosina, Estavudina, Lamivudina, Tenofovir, Zidovudina (AZT), Efavirenz, Nevirapina, Etravirina, Atazanavir, Darunavir, Fosamprenavir, Indinavir, Lopinavir/r, Nelfinavir, Ritonavir, Saquinavir, Tipranavir, Enfuvirtida and Raltegravir. See *MoH*, Antiretrovirals. For more information on the treatment, see *MoH*, HIV Infected Adults Antiretroviral Therapy Recommendation, p. 126-128.

652 See *Nunn*, *et al.*, Anti-retroviral Drug Cost in Brazil, p. 4-6.

sented almost 2% of the entire budget of the Ministry of Health. Importation of nelfinavir, efavirenz, lopinavir/r and tenofovir was responsible for 50% of these expenditures.[653] In 2005 and 2006, the government spent 11% of the Ministry's total expenditures only on the purchase of efavirenz.[654]

The increase in cost for the National Sexually Transmitted Diseases and AIDS Program is due to a combination of factors: a) each year there are more HIV carriers and AIDS patients initiating treatment; b) the treatment itself extends the lives of patients and, consequently, the term during which they will receive treatment; c) the longer the treatment period, the higher the risk and probability that patients will develop resistance to administered drugs, leading to the need for second and third generation antiretroviral drugs, which are more expensive and often patented; d) as of the enactment of Law 9279/1996, patenting pharmaceutical products is permitted, which restricts production of generic versions of drugs until patents expire; e) the national pharmaceutical industry does not have the technological capacity to produce generic versions of drugs covered by patents if compulsory licenses are granted; and f) more types of antiretroviral drugs are being used in order to include more innovative drugs in the anti-AIDS cocktail.[655] In order to maintain financial sustainability in the National Program, which reached its pinnacle in 2005,[656] the Brazilian government has adopted measures including national production of antiretroviral drugs, negotiations with the international pharmaceutical industry for price reductions, and granting of a compulsory license for efavirenz.

C. The Cases of Kaletra and Efavirenz

At the beginning of 2001, the Brazilian government announced that it was considering issuing compulsory licenses for the patents covering nelfi-

653 See 2005 Annual Budget Law; *MoH*, Antiretroviral drugs expenditure report; *MoH*, HIV Infected Adults Antiretroviral Therapy Recommendation, p. 129; See *Nunn*, *et al.*, Anti-retroviral Drug Cost in Brazil, p. 4-6.

654 See *MoH*, Antiretroviral drugs expenditure report.

655 See *Hoirisch*, Drugs Compulsory License as a Public Policy:_Efavirenz case, p. 64.

656 See *MoH*, Antiretroviral drugs expenditure report.

navir (marketed in Brazil by Roche under the brand Viracept) and efavirenz (owned by Merck, Sharp & Dohme and marketed under the brand Stocrin), two drugs used in the anti-AIDS cocktail administered to patients in the National Sexually Transmitted Diseases and AIDS Program.[657] In March 2001, the Ministry of Health and Merck started negotiations and in November of the same year agreed to an additional price discount of 59% (the new cost of daily treatment was reduced to US$2.52 from US$6.96 when the drug was first launched). This discount was in addition to the price already reduced by 11.7% in exchange for not granting compulsory licenses of the patented efavirenz drug.[658] In August 2001, a settlement was also reached between the government and Roche for a 40% discount after threatening to give a compulsory license for nelfinavir patents, which would be then manufactured by the state-owned laboratory FarManguinhos.[659]

On June 24, 2005, the Ministry of Health enacted Ordinance 985, declaring the medicine containing the combination of the active ingredients lopinavir and ritonavir to be in the public interest. The combination of the antiretrovirals lopinavir and ritonavir is marketed by Abbott under the brand Kaletra, which is also part of the cocktail of drugs used in the treatment of AIDS. The Ordinance affirms that its declaration of public interest follows Article 71 of Law 9279/1996, which allows the government to grant *ex officio* compulsory licenses in cases of national emergency and public interest, citing the impact of the drug's price on the public budget and the maintenance of the National Sexually Transmitted Diseases and AIDS Program.[660]

After publication of Ordinance 985/2005, the National Health Council issued Resolution 352 of August 11, 2005, stating that negotiations with the laboratories owning the patents covering efavirenz, lopinavir and tenofovir have failed to result in a significant price reduction. The Resolution ended negotiations, enabling compulsory licensing of the respective patents and determining the local manufacturing of the drugs by investments that would strengthen state-owned laboratories and increase resources for research and development. The Resolution's preamble alleges that the high cost of the drugs may jeopardize the long-term existence of

657 See *Rodrigues*, *Soler*, Efavirenz compulsory license in Brazil, p. 553-554.
658 See *Sanches*, Compulsory licenses: facts and myths, p. 5.
659 See *Roche*, Roche and Brazilian Ministry of Health agreement, para. 3.
660 See Ordinance 985/2005, Preambles, para. 4-5, 8.

the National Program,[661] but does not point out that the patent owners were using their economic power in an abusive manner. Nevertheless, on November 9, 2005, during a meeting of the National Health Council, the Minister of Health declared in a technical note that he would not ratify Resolution 352/2005, despite having initially signed it. Thus, the compulsory license for Kaletra, tenofovir and efavirenz patents would not be granted, since, contrary to Resolution 352/2005, negotiations with the patent owners were generally positive and should be reinstated.[662] It is important to note that the government's modus operandi always consists of threatening to grant compulsory licenses in order to obtain discounts on drug prices.

The settlement reached between the government and Abbott provided that Kaletra be supplied at a price of US$0.63 per tablet, as of February 26, 2006 and should be maintained until December 31, 2011. The new price represented a 46% reduction in the original price.[663] The agreement also established that Kaletra's new formulation, branded Meltrex, would be supplied at a 10% price increase.[664] The settlement with Abbott was shown to be more favorable for the government, since the national production of the drug would take at least two years and the lowest offer to the government for importing the drug was US$0.72, a higher price than Abbott's proposal.[665]

A civil class action was filed on December 1, 2005, by the Office of the Attorney General and NGOs against this settlement between Abbott and the Ministry of Health, seeking the granting of compulsory license of the Kaletra patents, arguing that national laboratories would be able to product the pills at US$0.41.[666] On May 8, 2006, the preliminary injunction was denied by the judge of the 15th Federal Trial Court of Brasilia. The decision was based on the lack of evidence concerning feasibility of the US $0.41 price and insufficient data regarding how the government would be able carry out the compulsory license, considering the investments needed

661 See Resolution 342/2005, Preambles, para. 4.
662 See *MoH*, 160ª CNS Ordinary Meeting Record, p. 4.
663 See *MoH*, Government and Abbott agreement, p. 2.
664 See *Id*., p. 3.
665 See *MoH*, Kaletra counterproposal, para. 4.
666 See *Ministério Público Federal v Abbott*, Initial Appeal, p. 11, 46-48.

to enable national facilities for production.[667] The Federal Court of Appeals for the 1st Circuit confirmed this decision, rejecting the preliminary injunction and affirming that the Brazilian government acted according to its best judgment with no evidence showing violation of the law simply because it is possible to have the drugs purchased at a lower price.[668] On June 25, 2010, the trial court judge rendered a final decision rejecting the granting of compulsory licenses.[669] The appeal filed before the Court of Appeals for the 1st Circuit is now pending.[670]

Since efavirenz was introduced in the anti-AIDS cocktail in 1999, its use has progressively increased from 2,500 patients in 1999 to 75,000 patients in 2007, or 42,29% of patients treated in that year.[671] Due to such a high number of patients, efavirenz was seen as a threat to public finances and expenditures with the anti-AIDS cocktail. In 2006, the Brazilian government started to negotiate the price of efavirenz with Merck, arguing that the international laboratory marketed the drug at a lower price in countries like Thailand with the same Human Development Index,[672] yet demand in those countries would not be as big as in Brazil. The government alleged that while only 17,000 people in Thailand were submitted to treatment, 75,000 patients in Brazil were taking efavirenz, and, in spite of this, the price the Brazilian government was being charged was US $1.5920 per tablet – much higher than the US$0.65 offered in Thailand due to generic competition after a compulsory license had been granted in that country.[673] Brazil requested a discount so as to obtain the same US $0.65 price as Thailand; Indian generic versions would be much cheaper

667 See *Ministério Público Federal v Abbott*, Preliminary Injunction Trial Court Judgment, p. 3.

668 See *Ministério Público Federal v Abbott*, Preliminary Injunction Appellate Court Judgment.

669 See *Ministério Público Federal v Abbott*, Process Consultation on Trial Court Judgment, para. 34.

670 To see, insert "200601000227328" on *Federal Court of Appeals for the 1st Circuit*, Process Consultation.

671 See *MoH*, UNGASS – HIV/AIDS: Brazilian progress in 2005/2007, p. 86-87.

672 Merck makes use of price differentiation for determining efavirenz price based on a country's Human Development Index or HIV patient number. The price of the drug ranges from US$277.40 to US$697.00 per patient each year. See *Hoirisch*, Drugs Compulsory License as a Public Policy: Efavirenz case, p. 77; *MoH*, compulsory licensing of Efavirenz, item 4; and *Merck*, Commitment to HIV/AIDS, p. 3-4.

673 See *MoH*, compulsory licensing of Efavirenz, item 4.

at a cost of US$0.427 to US$0.443 per tablet.[674] Negotiations with Merck evolved until the end of April 2007, when the laboratory's final proposal was a price of US$1.10, reducing 84% of its initial US$6.96 price in 2000,[675] which was deemed unacceptable by the Brazilian government.[676]

Unable to obtain the same discount offered to the Thai government, the Brazilian Minister of Health enacted Ordinance 886 of April 24, 2007, declaring that efavirenz was of public interest. The objective was to grant a compulsory license for non-commercial public use in order to guarantee feasibility of the National Sexually Transmitted Diseases and AIDS Program and safeguard the continuity of free and universal access to all medications needed for the treatment of HIV and AIDS.[677] The Ordinance expressly mentions the Doha Declaration and the recognition that WTO Member States are entitled to make full use of flexibilities in TRIPS when adopting measures to protect public health.[678] Despite new attempts at negotiation, in which Merck's US$1.10 offer was refused,[679] Decree 6108, of May 4, 2007, was enacted granting *ex officio* compulsory licenses of Brazilian patents PI1100250-6 and PI9608839-7 for public interest,[680] upon payment of royalties at 1.5% over the cost production or the price of the drug delivered to the Ministry of Health.[681] Patent PI1100250-6, a pipeline patent entitled "benzoxazinones as inhibitors of HIV reverse transcriptase" was granted on August 9, 1999, with expiration on August 7, 2012, composed of claims covering efavirenz compounds and pharmaceutical compositions.[682] Patent PI9608839, entitled "compound and compound N-(4-methoxybenzyl)-6-chloro-2[(R)-cyclopropylethynyl-hydroxy-trifluoromethyl]-methyl chiral aniline" was granted on June 21, 2005, with expiration on May 21, 2016, covering intermediate compounds in the process of obtaining efavirenz.[683]

The compulsory license has been granted for a five-year term (ending on May 7, 2012), but is renewable for an equal period without exclusivity

674 See *MoH*, UNGASS – HIV/AIDS: Brazilian progress in 2005/2007, p. 87.
675 See *Sanches*, Compulsory licenses: facts and myths, p. 5.
676 See *MoH*, Explanatory note, item 4.
677 Article 1 of Ordinance 886/2007.
678 See Ordinance 886/2007, Preambles, para. 6.
679 See *Sanches*, Compulsory licenses: facts and myths, p. 6.
680 Article 1 of Decree 6108/2007.
681 Article 2 of Decree 6108/2007.
682 To see, insert "PI1100250-6" on *INPI*¸ Patent Process Database, claims 1-5.
683 To see, insert "PI9608839-7" on *INPI*¸ Patent Process Database, claims 1-2.

and for non-commercial public use within the National Sexually Transmitted Diseases and AIDS Program and pursuant to Law 9313/1996 in order to provide for universal and free distribution of antiretroviral drugs.[684] Decree 6108/2007 determines that the license will be terminated by means of an act from the Ministry of Health once the circumstances of public interest cease to exist.[685] The royalties to be paid to Merck were established at 1.5% of the drug production cost or of the drug price upon delivery to the Ministry of Health.[686] Merck is obligated to supply all the necessary and sufficient information for the effective reproduction of the licensed patents[687] under the penalty of having the patents declared invalid for lack of enablement.[688] The exploitation of licensed subject matter should be primarily carried out directly by the federal government or by duly hired third parties.[689] Nevertheless, if it is not possible to satisfy the needs of public interest through the products placed in the domestic market, or if the total or partial production of the licensed subject matter by the government shows to be unfeasible, importation is allowed upon due payment of royalties.[690] For record keeping purposes, the Ministry of Health must inform the INPI of the granting of the compulsory license by means of Decree 6108/2007 as well as any modifications and termination.[691]

Brazil has not immediately started national production of efavirenz. At first, it imported the drug from Indian laboratories Aurobindo and Ranbaxy,[692] by means of the UNICEF and the Pan American Health Organization (PAHO – the regional office of the WHO for the Americas) respectively.[693] The first batch arrived in the country on June 2, 2007, at a final

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684 Article 1, paragraph 1 of Decree 6108/2007.
685 Article 1, paragraph 2 of Decree 6108/2007.
686 Article 2 of Decree 6108/2007.
687 Article 3 of Decree 6108/2007. Article 3 of the Decree 6108/2007 was outlined pursuant to paragraph 1 of article 5, item II of Decree 3201/1999.
688 Article 3, sole paragraph of Decree 6108/2007.
689 Article 4 of Decree 6108/2007.
690 Article 5 of Decree 6108/2007.
691 Article 6 of Decree 6108/2007.
692 The two Indian laboratories were selected among the manufacturers which already had efavirenz in the pre-qualification system established by the World Health Organization (WHO) meeting certain quality, safety and efficacy standards. See *Hoirisch*, Drugs Compulsory License as a Public Policy: Efavirenz case, p. 79; and *MoH*, compulsory licensing of Efavirenz, item 7.
693 See *MoH*, UNICEF and PAHO mediation; and *MoH*, UNGASS – HIV/AIDS: Brazilian progress in 2005/2007, p. 87.

cost between US$0.4270 and US$0.4430 per tablet.[694] The Ministry of Health initially estimated that national production would start by 2009 in the state-owned laboratories Farmanguinhos and LAFEPE.[695] The first batch manufactured by Farmanguinhos has not fulfilled the bioequivalence requirement after a change was introduced in the original formulation as an alternative to avoid importing one of the original ingredients; this eventually resulted in the need to import the ingredient and caused further delay for delivering a nationally manufactured efavirenz.[696] LAFEPE has not fulfilled a regulatory requirement of the ANVISA and Farmanguinhos remains the only laboratory manufacturing efavirenz in the country.[697] The first efavirenz pills produced by Farmanguinhos were sold at 45% of Merck's price (approximately US$0.67) before the compulsory license.[698] Farmanguinhos supplied 60% of the Brazilian demand and, until 2010, the remainder was still imported from India. This stock lasted until 2011, when the Brazilian supply became fully domestic.[699] The Ministry of Health ordered 57 million pills of efavirenz from Farmanguinhos in 2012 at approximately US$38.5 million.[700] It is estimated that around 50% of people in treatment (about 104,000 people) make use of efavirenz in their therapeutic regimen.[701]

On May 7, 2012, Decree 7723/2012 was published extending the term of the compulsory license of patents 1100250-6 and 9608839-7 covering efavirenz for public non-commercial use for another five years.[702]

Decree 4830/2003 was issued on September 5, 2003, amending the existing Decree 3201/1999 regulating the *ex officio* granting of compulsory licenses in the cases of national emergency and public interest, and specifically allowed the importation of the licensed patent subject matter in case the government or duly authorized third parties are not able to manufac-

694 See *MoH*, Positive Response; and *Hoirisch*, Drugs Compulsory License as a Public Policy: Efavirenz case, p. 78-79.
695 See *Agência Brasil*, Brazil starts producing generic against AIDS in 2009, para. 1.
696 See *Hoirisch*, Drugs Compulsory License as a Public Policy: Efavirenz case, p. 108-110.
697 See *Globo*, Nacional production of generic AIDS, para.7.
698 See *Estado de São Paulo*, Efavirenz price, para. 1.
699 See *MoH*, compulsory licensing of Efavirenz renew, para. 3.
700 *Id.*
701 *Id*., para. 1.
702 See article 1 of Decree 7723/2012.

ture it in the country. The provisions of the Decree should apply to the antiretroviral drugs used in the treatment of AIDS as facts of public interest should be understood to comprise issues related to public health.[703] The use of these antiretroviral drugs in the National Program does concern Brazilian public health, and the granting ex officio of compulsory licenses for public non-commercial use whenever the patent holder does not meet the needs of the public interest should be allowed. In the case of efavirenz, the public interest consisted in the government's budget for maintaining the National Program. With immediate savings of US$31.5 million,[704] pharmacoeconomic numbers in the Ministry of Health budget has illustrated the public interest. The primary interests of society are related to the budget and are reflected in the National Program context. Five years after the compulsory license was granted, foreign investments have not yet diminished in the country as the Brazilian government is still an important player for the global pharmaceutical industry because it remains a major purchaser of drugs (not only antiretroviral drugs).

The settlement between Abbott and the Brazilian government regarding the price of Kaletra has not brought an end to discussions revolving around patent PI1100397-9 covering lopinavir. In 2009, the Brazilian pharmaceutical company Cristalia filed a lawsuit before the 9th Federal Trial Court of Rio de Janeiro against Abbott seeking to invalidate pipeline patent PI1100397-9, entitled "compounds to inhibit retroviral proteases".[705] According to Cristalia, patent PI1100397-9 should be declared null because it was granted without examination of the patentability requirements including novelty, inventive step and industrial application (like the other pipeline patents), and without the prior consent of the ANVISA, in violation of Article 229-C of Law 9279/1996.[706] As a pipeline patent, it was granted in disrespect to the Brazilian constitutional provisions protecting acquired rights (society would have already acquired the right to use PI1100397-9 related subject matter as it would have already entered the public domain).[707] Cristalia argues that patent PI1100397-9 prevents competitors from manufacturing lopinavir until 2016, which would result in

703 See article 2, paragraph 2 of Decree 3201/1999.
704 See *MoH*, compulsory licensing of Efavirenz renew, para. 2.
705 *Cristália v INPI*, Trial Court Process.
706 *Cristália v INPI*, Trial Court Process, p. 2.
707 *Id.*

damages to the government's budget by increasing costs for the National Program and would restrict universal access to medications.[708]

The trial court judgment rendered on February 29, 2012, established that the patent was allowed by the INPI on November 23, 1999, prior to the enactment of Provisional Ruling 2006 on December 14, 1999, which first introduced Article 229-C into Brazilian legislation.[709] Accordingly, pipeline application PI1100397-9 should not be subject to the prior consent of ANVISA for final granting, as only the issuance of the letters patent upon payment of the due fees were still pending.[710] However, it declared that pipeline patents were unconstitutional; since novelty, which is one of the main requirements for granting a patent that justifies the existence of a patent system within the context of fostering innovation, cannot be found in this type of application.[711] The legal monopoly represented by a patent would be extremely detrimental to free competition, which is highly important in the pharmaceutical sector, a sensitive area regarding the welfare of society.[712] The judgment declared the unconstitutionality of patent PI1100397-9,[713] which only affects Abbott's patent that was under discussion, regardless of the constitutional lawsuit pending before the Supreme Court (ADIN 4234).[714] The appeal filed by Abbott against this judgment is currently pending before the Court of Appeals for the 2nd Circuit.

D. Impacts of the WTO Free Trading System on Brazil

As a result of Brazil's accession to the WTO free trading system, the country's commodities exports have experienced a boost. Total exports reached US$197.942 million in 2008 as a result of the increased volume of the country's participation in international trade since 1994.[715] Basic goods contributed at 36.9%, manufactured goods had a share of 46.8% and semi-

708 *Id.*
709 *Id.*, p. 8.
710 *Id.*
711 *Id.*, p. 12, 18.
712 *Id.*, p. 14, 18.
713 *Id.*, p. 18.
714 See footnote 384.
715 See *MDIC*, Evolution of Brazilian exports, line 55.

manufactured goods were at 13.7%.[716] During the global economic crisis, Brazilian exports experienced a small decline, but remained high in the amount of US$152.995 million with basic and manufactured goods maintaining a very close 40.5% and 44% respectively.[717]

In addition, the country has learned how to make use of the WTO system for its benefit as seen in the complaint against the United States for subsidies on upland cotton, which led to threats of retaliation regarding intellectual property rights.[718]

1. The Panel Against the US for Cotton Subsidies

On September 27, 2002, the Brazilian government requested consultations with the US under the WTO system of Dispute Settlement Understanding, questioning the consistency of US subsidies and export credit guarantee programs with the WTO Agreement on Agriculture and the Agreement on Subsidies and Countervailing Measures.[719] The panel that was established on March 18, 2003, issued its final report on September 8, 2004, finding that US subsides and export credit guarantee programs for unscheduled agricultural products, which include upland cotton and rice, circumvented the provisions of the Agreement on Agriculture and were not covered by the exemptions provided by the Agreement on Subsidies and Countervailing Measures.[720] The decision was confirmed by the Appellate Body, which issued its report on March 3, 2005.[721]

In compliance with the decision of the WTO Dispute Settlement Body (DSB), the US ceased their export credit guarantee programs, but continued to provide subsidies on upland cotton. Upon a Brazilian request to adopt countermeasures suspending its obligations to the US, a panel was established and found that the US had failed to comply with the recom-

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716 *Id.*
717 *Id.*
718 The WTO dispute settlement mechanisms should be considered a check and balance means for controlling the international legal order after the WTO and TRIPS has a key functional role with direct impacts in the balance of the global economy. See *Straus*, A Marriage of Convenience: World Economy and Intellectual Property, p. 662-666.
719 See *United States – Upland Cotton*, Key Facts, para. 1.
720 See *United States – Upland Cotton*, Report of the Panel, p. 347-351.
721 See *United States – Upland Cotton*, Report of the Appellate Body, para. 763.

mendations and rulings adopted by the DSB in the original procedure, as per a report issued on December 18, 2007.[722] On appeal, this understanding was confirmed by the report issued by the appellate body on June 2, 2008.[723]

As a result, Brazil requested authorization to implement countermeasures as well as to adopt retaliation measures on importation of goods, services and intellectual property rights.[724] An arbitration decision was rendered on August 31, 2009, establishing that Brazil was allowed to retaliate to the amount of US$829 million, authorizing cross-retaliation on services and intellectual property rights (under GATS and TRIPS respectively) for US$238 million.[725] The remaining US$591 million would result from retaliation on goods (under GATT 1994) by increasing tariffs for imports of US products such as cars, boats, wheat, ketchup and paracetamol, as listed by the Brazilian Chamber of Foreign Trade (CAMEX) in Resolution 15, of March 5, 2010.[726]

1.1. Cross-retaliation on IP rights

Article 22 of the DSU provides for retaliation in case official recommendations by the WTO Dispute Settlement Body have not been implemented in due course. Retaliation measures may consist of compensation and halting concessions or obligations deriving from WTO treaties and are considered temporary measures aimed at securing the implementation of the decision instated by the panel or appellate body. The general principle establishes that the concessions or obligations to be halted should first be within the same area in which the original violation of WTO provisions occurred; in case this is unfeasible or ineffective, sanctions should pertain to another section of the violated agreement.[727] In the latter case, as a sub-

722 See *United States – Upland Cotton*, Recourse to Article 21.5 of the DSU by Brazil, Report of the Panel, p. 188-190.
723 See *United States – Upland Cotton*, Recourse to Article 21.5 of the DSU by Brazil, Report of the Appellate Body, p. 175-178.
724 See *United States – Upland Cotton*, Communication from Brazil, para. 3.
725 See *United States – Upland Cotton*, Recourse to Arbitration by the United States under Article 22.6 of the DSU and Article 4.11 of the SCM Agreement, Decision by the Arbitrator, p. 124.
726 See *Brasil*, Brazilian retaliation list of products, para. 4.
727 See article 22.3 (a) and (b).

sidiary measure, cross-retaliation is possible, when other options are ineffective and the circumstances are serious enough, enabling suspension of concessions or obligations that fall under a completely different WTO agreement.[728]

Even before the end of the dispute settlement proceedings on US subsidies on cotton, following the favorable report published in 2007, bills of law were submitted to the Brazilian Congress aimed at establishing a procedure that would enforce an eventual cross retaliation. The most important piece was Bill of Law 1893/2007, which aimed at establishing measures to temporarily suspend or remove IP rights in Brazil in case of noncompliance with multilateral obligations under the WTO by a foreign State, and was conceived as a tool for commercial pressure. This measures affected copyrights including software, trademarks, geographical indications, patents, plant varieties, integrated circuit topographies and trade secrets comprising confidentiality of data packages.

The Brazilian President enacted Provisional Measure 482/2010 on February 10, 2010, which provided for measures suspending obligations related to the TRIPS Agreement as a form of retaliation under the WTO Dispute Settlement Understanding. This provisional measure was based on Bill of Law 1893/2007 and established measures against IP rights (copyrights including software, trademarks, geographical indications, patents, plant varieties, integrated circuit topographies and trade secrets comprising confidentiality of data packages) upon authorization by the WTO Dispute Settlement Body including a) reducing the term of protection for IP rights, b) providing compulsory licenses, c) allowing parallel importation of patented products, d) increasing official fees for obtaining and maintaining IP rights, e) temporarily prohibiting that royalties are remitted abroad, and f) creating a registration requirement for obtaining and maintaining IP rights.

Natural persons who are nationals or residents of countries against which Brazil has been authorized to retaliate, as well as companies therein headquartered or established, are affected by cross-retaliation. In the cotton dispute scenario, the measures would be applicable against US residents or nationals with IP rights in Brazil. Provisional Measure 482/2010 was fully approved by Congress, converted into Law 12279/2010, and came into force as of June 22, 2010.

728 See article 22.3 (c).

Following the enactment of Provisional Measure 482/2010, the Brazilian Chamber of Foreign Trade (CAMEX) published Resolution 16, on March 12, 2010, opening public consultation proceedings to hear interested parties regarding cross-retaliation measures against IP rights in the US cotton dispute. Following the general lines of the provisional measure, Resolution 16/2010 suggests a range of IP-related measures to be taken. They include: a) reduction of the term of protection for a certain period of time for patents covering medications for human and veterinary use, chemical and biotechnological products and processes for agriculture, IP rights on plant varieties, as well as copyright over public performance of musical works; b) royalty-free compulsory license of patents covering medications for human and veterinary use, chemical and biotechnological products and processes for agriculture, IP rights on plant varieties, as well as copyright over literary works and public display of audio-visual works; c) importation without consent of the patent holder of products protected by patents covering medications for human and veterinary use, chemical and biotechnological products and processes for agriculture, allowing parallel importation of branded drugs and importation of generics; d) increase of official fees charged by the INPI regarding patents, trademarks, utility models, industrial designs, software registration, geographical indications, integrated circuit topographies and record of licenses, as well as the fees charged by the Plant Variety Protection Office and by the entities responsible for copyright registration; e) application of commercial rights over royalties to be paid to owners of patents, trademarks and copyrights including software; and f) creation of mandatory registration as a requirement for obtaining and maintaining copyrights.

The enactment of Provisional Measure 482/2010 (at the time Bill of Law 1893/2007 was still pending in Congress) and the issuance of Resolution 16/2010, served as a tool for political maneuvering. US companies or citizens who owned or licensed IP rights in Brazil, as well as foreign companies located or with principal place of business in the US could be affected. Under assessment of the Brazilian government, retaliation on goods could pose trouble, but threatening to suspend patent protection for pharmaceutical products could result in pressure from the industry to push the US government to halt subsidies and to negotiate.[729] Moreover, sus-

729 See *Varella*, Effectiveness of DSB, p. 15-17; *Hoirisch*, Drugs Compulsory License as a Public Policy: Efavirenz case, p. 82-85.

pending IP rights would lead to a decrease in prices, benefiting consumers, whereas retaliating on goods would lead to price increase of products imported from the US.[730]

The provisions in the TRIPS Agreement were part of the package that developing countries had to accept in order to benefit from a multilateral trading system.[731] Thus, Brazil has been using all means available under the WTO system in order to ensure that the rulings by the Dispute Settlement Body are enforced.

1.2. Ongoing Discussions

As negotiations evolved with the US government, Brazil decided to postpone retaliations both on goods and IP rights until 2012, when the US Congress would vote on an agricultural reform bill (the Farm Bill), provided that a fund was created to support Brazilian cotton producers to the amount of US$147 million per year,[732] representing compensation, partial reduction and annual limitations on US subsidy programs.[733] The defeat of the governing party in the US congressional election on November 11, 2010, resulted in uncertainties regarding the approval of a new US Farm Bill that would reduce subsidies. In fact, the approval of an amendment to the 2012 agriculture budget by the US House of Representatives on June 16, 2011, posed a more serious threat to the agreement reached between the two countries. The amendment ended the US$147 million annual payments in order to reduce US public expenditures.[734] Nevertheless, the US Senate decided to maintain the payments.[735]

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730 See *Varella*, Effectiveness of DSB, p. 15-17.

731 For more on the relationship between GATT, TRIPS and the use of the WTO dispute settlement mechanism, see *Straus*, A Marriage of Convenience: World Economy and Intellectual Property, p. 642-654, referred by this author as a "marriage of convenience".

732 The Instituto Brasileiro do Algodão (IBA) has been discussing with the state associations of cotton producers the management of the and the activities and measures to be implemented, such as investments in environmental sustainability, infrastructure and training. See *Dinheiro Rural*, Interview with IBA president, p.1.

733 See *Id*.

734 See *Estado de São Paulo*, Resumption of the cotton case?, p. 1.

735 See *Farm Policy*, Senate Farm Bill Issues, p. 1.

As the new Farm Bill was being been discussed in the US Congress, the subsidies contested by the Brazilian government have been replaced by an income protection program named Stax, which is an insurance policy for cotton growers that assures the income of farmers will not fall below the expected regional revenues.[736] According to the statement by the Brazilian ambassador to the WTO, Roberto Azevedo, no program covering for such income losses is compliant with WTO and challenging IP rights seems to be the only way to engage the US.[737] In June 2012, the CAMEX decided to reactivate the working group that had been evaluating the issue of cross-retaliation.[738] A progressive reduction in the US federal budget as of March 2013 opened a new round of debates and the US Secretary for Agriculture announced that the US would suspend monthly payments to Brazilian cotton producers as of October 2013.[739] In response, the Brazilian Ministry of Foreign Affairs announced that cross-retaliation relating to IP rights and services was still on the table.[740]

With the final approval of the US Farm Bill providing for the Stax income protection program by the US Congress at the beginning of 2014 after several years of discussions,[741] and consequently the end of the temporary agreement reached with the US to postpone retaliations, it is now up to Brazilian officials to assess whether or not to exercise the right to cross-retaliate[742] and, hence, establish a precedent within the WTO trading system.[743]

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736 See *The Guardian*, Cotton subsides in farm bill, para. 12.

737 *Id*., para. 13, 17.

738 See *Brazil – US Business Council*, CAMEX, assess retaliation to US, para. 1, 3.

739 See *Estado de São Paulo*, the US suspend payment of indemnification to Brazilian producer, para. 3, 7.

740 See *Exame*, Brazil does not discard retaliating the US in the cotton case, p. 1.

741 See *Fox* News, Congress approves farm bill, sends to Obama for signature, para. 1, 7.

742 Already envisaging the approval of the US Farm Bill, the working group of CAMEX intensified its discussions on cross-retaliation and, on December 19, 2013, re-opened public consultations about the measures foreseen in Resolution 16/2010 by means of Resolution 105/2013. This new resolution seeks to reinstate internal proceedings within the CAMEX for a recommendation regarding the adoption or not of cross-retaliation in intellectual property rights, which should be established until February 28, 2014 pursuant to its article 4.

743 Cross-retaliation was also requested by Ecuador against the European Communities (see *European Communities – Regime for the Importation, Sale and Distribution of Bananas.* Recourse to Arbitration by the European Communities under

Despite settlements eventually reached, cross-retaliation against IP rights may run against some considerations regarding Constitutional Law. As discussed in the previous chapter, IP rights in Brazil are guaranteed under Article 5, XXVII and XXIX of the Constitution. Intellectual property is granted protection to be statutory regulated, keeping in mind the interests of society and technological and economic development of the country. This constitutional finalistic clause must underline the granting of patents along with any limitations to them.

Laws restricting fundamental constitutional guarantees are subject to limitations – entitled "limitations to limitations" – and requirements in order to safeguard such guarantees, which could otherwise become void.[744] The governing principle is the prohibition against excesses, according to which limitations should a) enable the intended purposes, b) be needed since there is not a less cumbersome way to achieve such purpose and c) be proportional demanding a reflected analysis of the burden caused and benefit brought.[745] Any law restricting a constitutional guarantee should comply with the three requirements; even if adequate and needed, it should be deemed unconstitutional if it adopts measures constraining rights that are excessive and are not proportional to the obtained results. The proportionality principle acts as a mechanism to limit and control ordinary laws passed by Congress.

Any legislation limiting IP rights, which are safeguarded as fundamental guarantee in the Constitution, should only be pursued in order to defend any other constitutionally protected rights or values. Limits should also comply with the following two requisites. 1) They should be proportionate, connecting the restriction with constitutionally foreseen goals. 2) The restriction should also aim at the economic and technological development of the country. Nevertheless, limits should respect the proportionality principle, paying attention to its adequacy, need, burden imposed, and benefits brought.[746]

Article 22.6 of the DSU, Decision by the Arbitrators, March 24, 2000 (WT/DS27/ARB/ECU), para. 173) and by Antigua against the US (see *United States – Measures Affecting the Cross-Border Supply of Gambling and Betting Service.* Recourse to Arbitration by the United States under Article 22.6 of the DSU, Decision by the Arbitrator, Deceber 21, 2007 (WT/DS285/ARB), para. 1.5). Upon the threat of cross-retaliation, these cases also reached a settlement.

744 See *Canotilho*, Constitutional Law and theory of the Constitution, p. 451.

745 See *Barroso*, Interpretation and application of the constitution, p. 209-234.

746 See *Leonardos, Maior*, Opinion on Bill of Law 1893/2007, p. 5.

Inasmuch as cross-retaliation on IP rights may be legally available under the WTO system and may be useful as a tool for political pressure, restriction of IP rights as foreseen in Law 12279/2010 are not directly linked to public interest, economic and technological development of the country, or any social function pertaining to these rights. The measures implementing retaliation on IP rights should be shaped by the Brazilian constitutional system. In this case, compulsory license of a certain patented technology with a provision mandating transfer of technology would retaliate on IP rights and serve the purposes of development, without being too excessive in case due royalties must be paid to the patentee.

2. Remarks on the Overall Pharmaceutical Scenario

The main argument against patent rights is the high prices of drugs. Since patents establish the right to exclude competitors, patents are not regarded as competition friendly; rather, they are an option taken for policy making reasons with the goal of fostering technological development. In reality, no extensive and corroborated empirical studies have been able to show the direct correlation between price increase with the introduction of patents covering pharmaceutical products and processes in Brazil.[747] A study carried out in 2003 pointed out that the average drug price in Brazil increased from US$1.31 to US$6.04 between 1989 and 1998.[748] Since patents for pharmaceutical have only begun to be effectively granted in the country as of the enactment of Law 9279/1996,[749] it is not possible to conclude that such increase is a direct result of patent protection in this field of technology.

Availing itself of the flexibilities provided by TRIPS, the Brazilian government has not stopped with the granting of compulsory licenses for efavirenz in the context of the National Sexually Transmitted Diseases and AIDS Program. Ordinance 681 of April 8, 2008, was issued by the Ministry of Health declaring tenofovir to be of public interest, taking into ac-

747 The author has carried out an extensive search and, to the best of her knowledge, no study has been published in this regard.

748 See *Valentim*, Generic Drugs Policies: a study of the Brazilian case, p. 21.

749 Studies indicate that the first patent for medicines in Brazil was granted in 1884. See *Assumpção*, Chemistry Patent in Brazil: A Troubled History, penultimate para.

count that the drug is an important component of the anti-AIDS cocktail. Tenofovir was the subject matter of patent application PI9811045-4, pending examination by the INPI since 1998, and the declaration sought to have the application subject to priority examination pursuant to INPI Resolution 132/2006.[750] The Resolution mentions that Fiocruz had already filed third party observations supporting the lack of novelty and inventive step of the application's subject matter, and that an application belonging to the same family was rejected in the US for lack of inventive step.[751] Acceleration of the application through priority examination was clearly a measure for having the patent denied by the INPI. The INPI ultimately rejected the patent due to unfulfilled patentability requirements of Articles 8 and 13 of Law 9279/1996.[752] Patent applicant Gilead Sciences, Inc. filed a lawsuit in Brazilian federal court on January 26, 2010, seeking to revert the decision by the INPI, which is currently pending a trial court decision.[753] National production of tenofovir began in 2011 by the state-owned laboratory Fundação Ezequiel Dias (Funed), and the first batch was put on the market in March 2011. According to estimates by the Ministry of Health, it could represent an economy of $410 million reais (approximately US$242 million) in five years.[754]

Current Brazilian President Dilma Rousseff gave a speech to the United Nations on September 20, 2011, in which she declared that Brazil defends access to medicine as part of the human right to health, as a strategic element for social inclusion, equity and strengthening of public health systems. She also stated that Brazil respects its commitments and obligations concerning IP rights, but is convinced that TRIPS and the Doha Declaration provide flexibilities that are indispensable for policies that safeguard the right to health. The President indicated that the government may make use of compulsory licenses for drugs for the treatment of non-transmissible chronic diseases such as cancer, hypertension, diabetes, and lung dis-

750 INPI's Resolution 132/2006 establishes in article 3 that patent applications which subject matter is declared by the government of national emergency or public interest – under the cases described in paragraphs 1 and 2 of article 2 of Decree 3201/1999 – will be subject of priority examination *ex officio*.

751 See Ordinance 681/2008, Preambles, para. 6-7.

752 See *RPI*, 1964, p. 114; and *RPI*, 2008, p. 23.

753 See *Gilead Sciences Inc. v INPI and ANVISA*, Process Consultation on Trial Court Judgment.

754 See *MoH*, AIDS and Hepatitis National Production.

eases.[755] Following the Brazilian President's speech, the Minister of Health Alexandre Padilha declared that such diseases are also public health concerns, as there should be no differentiation between transmissible and non-transmissible diseases and 72% of non-violent deaths among people under 70 are caused by such diseases. However, the Minister affirmed that it would not be a case of general issuance of compulsory licenses, and there are no upcoming plans or needs for compulsory licenses to be issued for medications used in the treatment of such diseases.[756]

On April 9, 2013, the INPI published Resolution 80/2013, which established rules on prioritized examination for patent applications of pharmaceutical products and processes as well as equipment and material relevant to public healthcare. Prioritized examination may be granted to requests by the Brazilian Ministry of Health for any application concerning products, processes, equipment or material for healthcare related to public assistance policies and regarded to be strategic to the SUS.[757] Any interested party, which includes applicants and third parties, may request prioritization whenever the patent application's subject matter is directed at diagnosis, prophylaxis and treatment of AIDS, cancer or neglected diseases.[758] The grounds for prioritization requested directly by the Ministry of Health are not restricted to patent applications covering diagnosis, prophylaxis and treatment of the diseases listed in the attachment.[759] Entitlement of the Ministry is broader so as to encompass any application regarded as strategic to the public healthcare system. Therefore, in the tenofovir case, the speech at the UN and the INPI Resolution 80/2013 serve as evidence that the Brazilian government will make use of the tools available in the patent system to implement public health policies.

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755 See *MoH*, Clipping – Chronic Diseases and Patents Breaks.

756 See *Id*.

757 Article 1, paragraph 1 and article 3 of Resolution 80/2013.

758 Article 1, paragraph 2 and article 5 of Resolution 80/2013. The neglected diseases are listed in Attachment 1 of Resolution 80/2013 as follows: Chagas disease; dengue, hemorrhagic dengue; schistosomiasis; hanseniase; leprosy; leishmaniasis; malaria; tuberculosis; Buruli ulcer; neurocysticercosis; echinococcosis; yaws; fascioliasis; paragonimiasis; filariasis; rabies; helminthiasis; manifestations originated from intoxications or poisonings caused by poisonous and venomous animals.

759 Article 3, paragraph 1 of Resolution 80/2013.