BACKGROUNDER

CONFLICT BETWEEN IMPROVED ACCESS AND PROTECTIONISM

Introduction

In the past few years, a number of countries have accelerated efforts to fight the spread of HIV/AIDS. They have included antiretrovirals drugs as part of their campaigns. However, some countries may be tempted to try to support local industry, which can hinder the success of these efforts and create breaches in international agreements designed to encourage the introduction of innovative drugs.

Background

For example, since 1996 Brazil has substantially increased access to HIV/AIDS drugs for its population. Due to *unequivocal political commitment* demonstrated through legislation entitling citizens to free care and treatment, the government of Brazil has been committed to fight AIDS publicly and firmly at an early stage in the AIDS epidemic in that country.

Brazil has been able to significantly increase the number of people treated for AIDS from 24,000 in 1996 to 90,000 in 2000. Furthermore, expansion of HAART (highly active anti-retroviral treatment) in Brazil has reduced opportunistic infections and the number as well as duration of hospitalizations for HIV/AIDS related conditions. This reduction has resulted in health budget savings of $472 million.

While the Brazilian constitution guarantees free health care to all Brazilian citizens, what differentiates HIV from most other diseases in practice is that the government pays for the most modern therapy available; in other cases, therapy and care is often more basic. The government has taken concrete steps to enhance the accessibility to care as well as conducting large-scale public awareness campaigns.

A reasonably good public health infrastructure with well-equipped hospitals, testing laboratories, adequate numbers of trained personnel, and an effective national system for drug distribution are major factors in this success. *World Bank funding* played an important role in enabling the above scale up of infrastructure capacity for treating HIV/AIDS with HAART.

The problem: industrial policy versus health policy

However, the Brazilian government and some activists are promoting the implementation of local production in developing countries as an effective solution for improving access to medicines. They claim that local production plays a role in making the above success. Recently, Brazil's legislation, which requires all patentholders to manufacture products inside Brazil in order to maintain their rights, was challenged in the World Trade Organization (WTO). Some claim that the pending US-Brazil WTO case is about access to medicines.... *which it is not*. Here is why:

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Facts about local production in Brazil

- In 1996, *Brazil passed a good patent law that was largely compliant with the WTO TRIPS agreement on intellectual property.* By improving its patent system, Brazil attracted $2.1 billion dollars in multinational pharmaceutical investment between 1996 and 2000, creating jobs and boosting Brazil tax and revenues and exports.

- Unfortunately, *Brazil chose to retain a controversial measure of its old patent system that punishes patent owners who import their products rather than manufacturing them in Brazil.* Article 68, requires local working on all patented technologies (from pharmaceuticals to aircrafts) within three years of issuing the patent. Importing the product is not enough to maintain the patent, according to this law.

- This local working provision is *a clear violation of the TRIPS agreement* Article 27.1 which states: "…patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether patents are imported or locally produced."

- Thus, the intent of the Brazilian law is to *protect local manufacturing capacity, not to benefit patients.*

- *This provision affects all patented products, not just pharmaceuticals.* Concretely, this means that any sector of business be it information technology, machinery, chemistry, etc. will be required to manufacture locally in Brazil if it is to enjoy its patent rights. This is clearly an industrial policy that seeks to protect national business interests, not improving access to medicines.

Why local production does not solve the challenges of improving access to medicines.

- *The Brazilians cannot supply all of their own needs for ARVs through local producers.* Local manufacturing facilities can only provide 18% of all needed antiretrovirals drugs purchased by the Brazilian Ministry of Health – the remaining 81% are purchased from multinational companies.

- *Local production does not necessarily mean prices are reduced so as to improve access.* Reduction in prices for most antiretrovirals currently used in Brazil have been achieved, partly through the use of local manufacturing, yet the cost of triple therapy has been reduced by an average of only around 35%. Estimates are that triple therapy is available in Brazil at US$4137 per person per year.

- *Local production is not reliable.* The Brazilian government has had the experience of awarding contracts to local producers, only to discover later that the local producer cannot make the product in sufficient quantities or quality to meet its commitments or demand.

- *The government-supported local manufacturers, which form the backbone of the local production of AIDS drugs, are not financially sustainable.* The local producers making AIDS drugs have consistently operated at significant losses over the past years. These losses are subsidies, as the government always supplies the necessary funds for operating these labs. In fact, in the past 12 months, the Ministry of Health has transferred US$50 million to state-owned labs to make up for their operating losses. Thus, the commitment to State-owned labs is not sustainable.

- The Brazil argument for compulsory local production if adopted by other countries around the world would actually *lead to less access to medicines*. It is obviously inefficient to have a production facility in each country on such an economy-of-scale as the pharmaceutical industry.

- *Compulsory licensing regimes have been shown by experience to discourage investment and the introduction of new products into a market.* Brazil's itself experienced a strong inflow of investment after strengthening its patent law after 1996. A weakening of its patent regime would have an opposite effect.

- *If Brazil's local production requirements are maintained, it could lead to negative effects for Brazil.* Other countries could initiate similar "local production" requirements for products which Brazil exports such as aircrafts, then discriminating against Brazilian exports. This could be true for any country.

- *Many of the AIDS drugs on the Brazilian market are not under patent in Brazil*; thus a compulsory license would be irrelevant to these products.

- *The Fact that patents are not the problem for obtaining access to drugs is well shown by the Brazilian population's inadequate access to drugs to fight tuberculosis, which are already off patent.* According to WHO studies, only 5% of Brazilians living with TB have access to DOTS therapy, which is recommended by WHO as a highly cost effective curative treatment for TB.

Evidence from around the world shows that strong intellectual property rights are the engine that has driven the discovery of the current arsenal of effective antiretrovirals, and they remain vital to spur further innovation, which is indeed the only hope for an eventual cure for AIDS.