Health and ‘intellectual property’

Poor nations and drug firms tussle over WTO patent provisions

By Gumisai Mutume

In April, 39 pharmaceutical companies withdrew a lawsuit they had filed against the government of South Africa to block it from making cheaper medicines available to its people. The case was widely seen as a test of the ability of the poorest countries to import or license the manufacture of life-prolonging drugs at prices affordable to the millions who need them.

By dropping their suit, the companies signalled their unwillingness to continue contesting governments’ ability to take advantage of access provisions of the World Trade Organization (WTO) agreement on intellectual property rights. The agreement — known as trade-related aspects of intellectual property rights (TRIPS) — was part of the 1994 Uruguay Round of trade liberalization measures adopted by countries that later formed the WTO. It has become the focus of public attention as developing countries that have been hit hard by the HIV/AIDS epidemic try to serve the health needs of their people, while still complying with its provisions.

African governments have asked WTO’s TRIPS Council — which monitors implementation of the agreement — to consider their concerns about the way intellectual property rights and patents are preventing poor countries from obtaining medicines needed to fight illnesses plaguing the continent. Mr. Tadeous Chifamba of Zimbabwe, Africa’s chief negotiator at the WTO, said they hope to obtain “further legal clarity” in the interpretation and application of the relevant TRIPS provisions, especially in countries faced by epidemics such as HIV/AIDS.

TRIPS obligations

TRIPS requires the 140 WTO member governments to give copyright and patent protection for 20 years to a wide range of new products, including pharmaceutical goods. During this period, no one may use, make or sell a product without the owner’s authorization. After the patent expires, other firms can sell “generic” versions of the product. TRIPS also protects trademarks and trade secrets.

Developed countries had until January 1996 to adopt domestic legislation that would make them TRIPS compliant. Most developing countries and former Soviet bloc states were required to conform by 2000, while the least developed countries (LDCs) have until January 2006 to comply. These poorest countries, however, can apply to the WTO for more time to come into compliance. For many governments, this has meant strengthening the protection and enforcement of intellectual property rights in their territories. Countries that fail to adopt national legislation in keeping with TRIPS can incur penalties, including trade sanctions.

TRIPS lays down the minimum standards for providing protection to patent holders, but these rights are not absolute. “The present regime of international trade agreements has been designed to strike a balance between the rights of patent holders and the rights of patients,” Dr. Gro Harlem Brundtland, director general of the World Health Organization (WHO), told participants in a recent forum held in Norway and sponsored by the WHO and WTO. “The TRIPS agreement contains important public health safeguards,” she added. Those “safeguard provisions” allow countries to override TRIPS requirements by engaging in compulsory licensing, parallel importing and invoking the so-called “Bolar” provisions (see box).

Public goods versus private profit

India and Thailand are two of the countries that allow companies to produce generic versions of drugs patented in industrialized countries, using alternative production methods from those developed by the original manufacturer. The drugs are then sold at very low cost to other developing countries. Within seven years of the introduction of ciprofloxacin — used to prevent intestinal infection by people with HIV — 48 companies in India were producing generic versions, despite the fact that it is under patent in Europe and the US.

Cipla, a company in India, recently attracted public notice when it offered its version of a “triple cocktail” of anti-retroviral drugs used in the fight against HIV to African governments

TRIPS safeguard provisions

Compulsory licensing. The term actually used in the agreement is “other use without authorization of the right holder.” It allows governments to permit a person other than the patent holder to produce the product without the owner's consent. Before the license can be awarded, the applicant must try to obtain a voluntary license on reasonable commercial terms. If a compulsory license is issued, a market-rate fee must be paid to the patent holder, the license can be used only in the domestic market and it must be rescinded once conditions change. Nothing in TRIPS limits the grounds on which governments can authorize the compulsory licensing of a patented product. Furthermore, in the event of a national emergency, a compulsory license can be issued without first trying to seek permission from the owner of the patent.

Parallel importing. Governments can permit parallel importing, in which a product manufactured under a patent held in one country but sold at lower prices in another country, can be imported from that second country without permission from the patent holder. TRIPS states that governments permitting parallel imports cannot be challenged under the WTO dispute settlement system, provided they do not discriminate on the grounds of the nationality of the patent holder.

Bolar provisions. The “Bolar” provisions allow generic manufacturers to prepare production and regulatory procedures before patents expire so that products can be ready for sale as soon as the patent ends, rather than having to go through the lengthy preparatory process only after the patent period is over.
for $600 per person for a year’s course of treatment and to a non-governmental organization (NGO) working in Africa for $350 for the same course. Combinations of three anti-retroviral medications — the “triple cocktails” — are now commonly used to fight the virus, which causes AIDS. They have transformed HIV-positive status from a life-ending condition to a potentially life-prolonging one. In the US, these same drugs cost between $10,000 and $15,000 per year.

Globally, pharmaceutical companies are putting pressure on governments and others not to purchase medicines from manufacturers of generic drugs. The latter firms replicate existing pharmaceuticals but do not research and develop new products. Yet without access to extremely inexpensive medications, the poorest countries — especially in sub-Saharan Africa — cannot afford the drugs needed to fight killer diseases such as tuberculosis, malaria and HIV/AIDS.

David and Goliath

The situation, however, still is far from clear. Neither Brazil nor South Africa — two developing countries that have been bold enough to interpret patent laws for the benefit of their populations — has been spared international legal challenges. Brazil was accused by the US of violating TRIPS provisions, in a case before the WTO Dispute Settlement Body.

In 1996, Brazil passed a law authorizing the local production of five key anti-retroviral drugs used in the US. Some of the medications, such as AZT, an anti-retroviral drug that prevents the transmission of HIV from mother to child, were patented prior to 1995 when the WTO provisions first applied. These medicines fall outside the scope of TRIPS. Through its patent law, Brazil allows the drugs to be produced legally, without paying royalties. As a result, Brazil is able to provide free drugs to people living with HIV/AIDS. Recently, Brazil managed to persuade the US company Merck to lower the prices of two of its drugs, Crizivan and Stocrin, used to treat people with AIDS, by threatening to permit compulsory licensing if Merck did not cut prices by 50 per cent.

In the US government’s view, a section of Brazil’s law discriminated against foreign owners of patents. Under the law, designed to help build a national pharmaceutical industry and reduce the price of medicines, Brazil will honour a patent only if the drug is produced locally. Therefore, foreign companies must establish a presence in Brazil in order to enjoy protection. According to the US, TRIPS prohibited this kind of discrimination. The US government maintained steady diplomatic pressure on Brazil to get it to change its patent regime and medicines policy, backing up the pressure with a threat of unilateral trade sanctions.

Last year, Ghana attempted to purchase low-cost AIDS drugs from the generic manufacturer Cipla. The patent holder, GlaxoSmithKline, warned that the product was under patent in Ghana and, while government officials disagreed, the deal was dropped. GlaxoSmithKline eventually conceded that it had made an error.

With the spread of national legislation enshrining minimum standards of intellectual property rights protection, actions a government now can take depend on what legislation it may already have adopted to prevent generic production or give exclusive marketing rights to patent holders.

In the 1990s, the US persuaded a number of countries to strengthen their intellectual property laws earlier than required by the WTO’s schedule by using the threat of trade sanctions. One provision of US trade legislation allows Washington to unilaterally impose sanctions on a country’s exports if that country fails to meet certain standards. After first threatening sanctions against South Africa, then President Bill Clinton later signed an executive order relaxing US intellectual property rights law in connection with the provision of HIV drugs in sub-Saharan Africa. The order bars any US agency from threatening WTO action or claiming violation of US patent law in order to discourage sub-Saharan African countries from producing or acquiring AIDS drugs.

What African LDCs can do

Brazil is often cited as an example African states could follow. “Except for a few countries that have existing patent laws, many countries in sub-Saharan Africa could go ahead and produce generic drugs or undertake parallel importing without raising any attention from pharmaceutical companies,” says Mr. Mark Grayson of the Pharmaceutical Research and Manufacturers of America, a powerful lobby group that has sought action to shore up prices in South Africa.

“Only a handful of African countries such as Kenya, South Africa and Zimbabwe have patent protection laws.” Since TRIPS gave a 10-year grace period to countries that did not already provide patent protection for pharmaceutical products when the agreement came into force in 1995, most African countries have until the beginning of 2006 before they must conform. Until then, many could follow Brazil’s example. Of the 13 countries that have applied to the WTO to extend the period in which they must comply with TRIPS, none are in sub-Saharan Africa. “What is surprising is that no African country has aggressively pursued the mechanisms in the WTO agreement,” says Mr. Salih Booker, executive director of the US-based advocacy group Africa Action.

Dr. Glaudine Mtshali, health attaché at the South African Embassy in Washington, DC, told Africa Recovery that in adopting the 1997 Medicines Act, South Africa “put into legislation the exemptions that TRIPS allows, enabling us to undertake compulsory licensing. But this only pertains to pharmaceutical products.”

Given the pharmaceutical companies’ decision to drop their law suit against South Africa, commented Ms. Ellen ‘t Hoen, legal advisor at the Paris-based non-governmental organization Médecins sans Frontières, “We don’t think the drug companies will be taking another developing country to court anytime soon.”

However, Oxfam, the UK-headquartered international relief and development NGO, believes that TRIPS still needs to be amended to improve the situation for poor countries. Along with other NGOs and some governments, it is lobbying to change TRIPS. Oxfam hopes to use the WTO’s regular biennial TRIPS review, next scheduled for 2002, to revise TRIPS so that developing countries have greater freedom to decide the duration and scope of pharmaceutical patents, exempt medicines from patenting and permit the local manufacture of patented products as part of their national development strategies.

African governments have concerns about the way intellectual property rights are preventing poor countries from obtaining medicines needed to fight illnesses plaguing the continent.