PATENT PROTECTION AND ACCESS TO HIV/AIDS PHARMACEUTICALS IN SUB-SAHARAN AFRICA

A Report Prepared For
THE WORLD INTELLECTUAL PROPERTY ORGANIZATION
(WIPO)

INTERNATIONAL INTELLECTUAL PROPERTY INSTITUTE

The International Intellectual Property Institute (IIPI) is a nonprofit, nonpartisan organization dedicated to improving intellectual property systems around the world, thereby fostering global creativity and serving as a catalyst for world economic growth. Since 1998 the IIPI has undertaken projects aimed at teaching the use of the intellectual property system as a tool of economic, social and cultural development by all countries.

For further details contact:

International Intellectual Property Institute (IIPI)
201 Massachussetts Avenue, N.W., Suite C-3
Washington, DC 20002
Phone: (202) 544-6610
Fax: (202) 478-1955
www.iipi.org

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Bruce A. Lehman, President

Abbreviations and Acronyms

AIDS	Acquired Immune Deficiency Syndrome
ARIPO	African Regional Intellectual Property Organization
ARV	Antiretroviral
DSB	Dispute Settlement Body (of the World Trade Organization)
DSU	Understanding on Rules and Procedures Governing the Settlement of Disputes (of the World Trade Organization)
EU	European Union
GATT	General Agreement on Tariffs and Trade
GSP	Generalized System of Preferences
HIV	Human Immunodeficiency Virus
IGO	Intergovernmental Organization
IPR	Intellectual Property Rights
LDC	Least Developed Country
MFN	Most-Favored Nation
MTN	Multilateral Trade Negotiations
NGO	Non-governmental Organization
OAPI	African Intellectual Property Organization
R&D	Research and Development
TRIPS	Agreement on Trade-Related Aspects of Intellectual Property Rights
UNAIDS	Joint United Nation Programme on HIV/AIDS
UNCTAD	United Nations Conference on Trade and Development
UNFPA	United Nations Population Fund
WHO	World Health Organization
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

Overview

This report examines the role that patents play in access to pharmaceuticals in the HIV/AIDS crisis of sub-Saharan Africa. The report aims to provide unbiased information about the international patent regime, the current patent status of certain HIV/AIDS drugs in sub-Saharan Africa and opportunities that exist through flexibility in international patent law that may help to improve access to HIV/AIDS drugs in that region.

The report concludes that providing state-of-the-art HIV/AIDS therapies to patients in poor countries requires two kinds of subsidies. The first is the indirect subsidy which consumers in developed countries pay in the form of higher prices for patented drugs. The patent incentive in countries such as the United States induces the free market to test and develop new products. Without the patent incentive, life-sustaining AIDS therapies would simply be unavailable even to the wealthiest consumers. The second kind of subsidy is direct funding of the treatment infrastructure and the purchase of drugs for patients in poor countries by the governments of developed countries acting in concert with one another through international programs such as UNAIDS.

It is unfortunate that the debate over patent protection has obscured the fact that current levels of foreign assistance – such as the USD 300 million proposed by the Clinton Administration for Fiscal Year 2001 – are not even remotely adequate to support these infrastructure and drug purchase costs. This is true under any scenario, whether it is the manufacture and use of generic pharmaceuticals or the use of deeply discounted drugs made available under license from patent holders. In effect, the inadequate financial commitment by the United States and other wealthy countries guarantees that many millions of infected Africans will not receive life-sustaining treatments now taken for granted in the developed world, and that these men, women and children will die when they might otherwise live.

In January of 1999, when the International Intellectual Property Institute (IIPI) was founded, IIPI proposed a pilot project to deliver patented therapies and other treatments to HIV/AIDS patients in developing countries based on a tiered pricing model. The project contemplated an integration of policy and technical approaches to expand access to HIV/AIDS drugs. The policy approach included principles of tiered pricing, together with national exhaustion and subsidized pharmaceutical purchases. The technical approach was based on sophisticated information systems, established models of patient care and controlled pharmaceutical delivery. Developments since this project was conceived have demonstrated the viability of these approaches, as well as the need for greatly expanded financing for them to succeed. It has become abundantly clear that whether the purchase of generic or patented drugs is contemplated, financing is critical.

Due in no small measure to the efforts of NGOs and health activists, the issue of access to affordable drugs has been placed at the forefront of the agenda in battling

HIV/AIDS. The 13th International AIDS Conference in Durban, South Africa in July 2000 focused the world's attention on the health crisis in Africa and the urgent need to improve access to drugs. Governments, industry and activists have been grappling with the issues that affect access to life-saving medicines, and are attempting to find solutions to these problems. Governments are seeking to find the appropriate balance between encouraging innovation in the pharmaceutical sector through intellectual property protection and making life-saving drugs more widely available.

The United States, the European Union and Japan, home to the bulk of the research-based pharmaceutical industry, have endorsed, in several multilateral settings, the need to find solutions to the problem of access to medicines for the developing world. They recognize that encouraging innovation in the pharmaceutical sector through the patent system must be balanced with the urgent need to make life-saving medicines more widely available. In a somewhat dramatic policy shift, both the United States and the European Union during the past year have softened their opposition to compulsory licensing and parallel importation of patented drugs. In addition, they have endorsed expanded mandates for the World Health Organization to provide advice to countries on intellectual property matters and to make pharmaceutical pricing information more transparent. There appears to be an emerging trend in favor of exploring all possible solutions to the problem of affordable access to HIV/AIDS drugs.

This report seeks to determine the extent to which patents for pharmaceuticals pose an impediment to the access of HIV/AIDS drugs in sub-Saharan Africa. The issue of access to affordable drugs involves numerous and complex issues, including health care infrastructure, international pricing mechanisms, financing, debt, tariffs and patents.

Even without patents or the WTO requirements under the TRIPS Agreement, HIV/AIDS drugs are, for the reasons set out above, beyond the reach of people in need. In some countries, even the basic medicines needed for treating non-HIV ailments are not affordable or available. Clearly, efforts to enhance access to HIV/AIDS drugs will require much more than merely looking at the patent issue. Nevertheless, patent issues and intellectual property rights cannot be ignored in the debate and must be addressed. It is our hope that this report will elucidate the issues surrounding the international debate concerning the role that intellectual property standards and patents play regarding access to HIV/AIDS drugs.

Chapter 1 of this report outlines the magnitude of the HIV/AIDS crisis in sub-Saharan Africa, and reviews the response of the international community, including the growing chorus calling for enhanced access to affordable drugs. Chapter 2 reviews the international patent regime established under the WTO TRIPS Agreement and in particular focuses on those provisions relevant to the issue of pharmaceuticals. Chapter 3 looks at the patent situation in sub-Saharan Africa, and particularly at the situation with regard to the protection of anti-retroviral HIV/AIDS drugs in the region. The results of IIPI surveys of patent offices and pharmaceutical

companies are also presented in Chapter 3. Following this analysis, conclusions are presented in Chapter 4, and recommendations, including specific recommendations directed to the World Intellectual Property Organization, are presented in Chapter 5. The report also includes country profiles that provide basic relevant information for each sub-Saharan country in continental Africa in Chapter 6, and concludes with a glossary of terms for reference.

Perhaps the most important conclusion of this report is that the TRIPS Agreement is not an impediment to the distribution of HIV/AIDS pharmaceuticals. It does not yet apply to the majority of sub-Saharan African countries, and where it does, it permits sufficient flexibility for countries to avoid negative effects. Similarly, patents are not an issue in access to drugs in sub-Saharan African countries, since most drug companies have not obtained patents widely in Africa. The real issue, this paper concludes, is that of adequate financing of the overall health system and the development of health care infrastructures.

It is for this reason that the primary recommendation of this report is that WIPO undertake efforts to correct perceptions that may lead to the conclusion that intellectual property protections in some way contribute to the lack of distribution of HIV/AIDS drugs and that it become a more active player in international debates on the subject. The report also recommends that WIPO strengthen its collaboration with the organizations involved in this area.

The International Intellectual Property Institute hopes that this report will help to enlighten these international debates on access to affordable drugs and encourage further research into the role that patents and the TRIPS Agreement play, or do not play, in this regard.

Bruce A. Lehman
President
International Intellectual Property Institute

1. HIV/AIDS Crisis in Sub-Saharan Africa

AIDS is now the leading cause of death in sub-Saharan Africa. Since the epidemic began, some 15 million Africans have died from AIDS and there are nearly 25 million adults and children living with HIV/AIDS in African countries south of the Sahara Desert.[1] There were 4.0 million new infections in this region during 1999. There are now 16 countries in which more than one-tenth of the adult population is infected with HIV. In seven countries at the southern cone of the continent, the infection rate exceeds 20 percent. [2]

Estimates of adult infection rates for the countries hardest hit by the HIV/AIDS epidemic in sub-Saharan Africa, as of the end of 1999, are shown below:

BOTSWANA	**35.80%**	**KENYA**	**13.95%**
SWAZILAND	**25.25%**	**CENTRAL AFRICAN REPUBLIC**	**13.84%**
ZIMBABWE	**25.06%**	**MOZAMBIQUE**	**13.22%**
LESOTHO	**23.57%**	**DJIBOUTI**	**11.75%**
ZAMBIA	**19.95%**	**BURUNDI**	**11.32%**
SOUTH AFRICA	**19.94%**	**RWANDA**	**11.21%**
NAMIBIA	**19.54%**	**IVORY COAST**	**10.76%**
MALAWI	**15.96%**	**ETHIOPIA**	**10.63%**

The HIV/AIDS epidemic poses an enormous threat to development in sub-Saharan Africa, which accounts for more than 70 percent of all HIV/AIDS cases globally. HIV/AIDS has reversed social, economic and political gains made over the past three decades in several countries.[3] As starkly put by the International Partnership Against AIDS in Africa, "[t]he speed, spread and scope of the epidemic is unprecedented in modern times…By threatening a generation of youthful, productive people, the disease is mortgaging the continent's future."[4] The devastating effects of HIV/AIDS in sub-Saharan Africa, predicted since the early 1990s, is now being seen in falling life expectancies, increasing numbers of orphans, and terrible tolls on households, learning, teaching, health systems, agriculture and business sectors across the board.[5]

The Worldwatch Institute, a nonprofit public policy research organization dedicated to informing policymakers and the public about emerging global problems and trends, recently published an "Issue Alert" noting the precipitous fall in life

[1] World Bank Press Release, "World Bank Steps Up Fight Against AIDS in Africa", 14 September 2000.
[2] Report on the Global HIV/AIDS Epidemic, UNAIDS/00.13E (English original, June 2000) (ISBN: 92-9173-000-9), pp. 8-11.
[3] UNAIDS Press Release, "UNAIDS Calls on G8 for Massive Increase in Resources to Fight AIDS", Geneva, July 20, 2000 (at www.unaids.org/whatsnews/press/eng/geneva200700.html).
[4] "AIDS in Africa: Development in Crisis", The International Partnership Against AIDS in Africa, UNAIDS/00.11E, May 2000, p. 2.
[5] Report on the Global HIV/AIDS Epidemic, pp. 21-36.

expectancies in sub-Saharan Africa.[6] Without AIDS, life expectancy in the year 2010 in Zimbabwe would be 70 years, in Botswana 66 years and in Zambia 60 years. With AIDS, these life expectancies are expected to drop to 35 years in Zimbabwe, 33 years in Botswana and 30 years in Zambia, "more akin to those of the Middle Ages than of the modern age." By 2010, Africa is expected to have 40 million orphans.[7]

About 95 percent of HIV-infected people live in developing countries, most of them in sub-Saharan Africa. At the same time, African governments together owe more than USD 230 billion in debt, with repayments costing Africa USD 15 billion each year – the equivalent of 5 percent of the region's income and about 15 percent of its export earnings.[8]

Despite concerted and intensified efforts to address the HIV/AIDS crisis, however, the epidemic rages on in several sub-Saharan African countries with more devastation than even the worst estimates predicted. In 1991, it was estimated that 9 million people would be infected and 5 million would die from HIV/AIDS in sub-Saharan Africa by the end of the decade, whereas in reality the figures are almost triple those predicted: 24 million infected and 13.7 million dead.[9]

[6] "HIV Epidemic Restructuring Africa's Population", Lester R. Brown, Worldwatch Issue Alert, 31 October 2000 (available at www.worldwatch.org).
[7] Ibid.
[8] UNDAIDS Press Release, "UNAIDS Calls on G8 For Massive Increase in Resources to Fight AIDS", Geneva, July 2000 (at www.unaids.org)
[9] "AIDS in Africa: Development in Crisis" at p. 2.

1.1 The International Response

The international community has mobilized to fight the HIV/AIDS epidemic in Africa on several fronts, involving international organizations, non-governmental organizations, industry and governments. Key players include:

UNAIDS, the leading advocate for global action on HIV/AIDS formed in 1995, which brings together seven UN agencies in a common effort to fight the epidemic: the UN Children's Fund (UNICEF), the UN Development Programme (UNDP), the UN Population Fund (UNFPA), the UN International Drug Control Programme (UNDCP), the UN Educational, Scientific and Cultural Organization (UNESCO), the World Health Organization (WHO) and the World Bank;

The International Partnership Against AIDS in Africa, a coalition uniting, under the leadership of African governments, the United Nations system of organizations, including UNAIDS, donor governments, and the private and community sectors;

The **World Bank** and **International Monetary Fund**, which launched the Heavily Indebted Poor Countries Initiative (HIPC) in 1996 and enhanced it at their joint meeting in September 1999 to accelerate debt relief of the poorest countries with unsustainable levels of debt;

The World Bank's multi-sectoral **AIDS Campaign Team for Africa** (**ACTafrica**) supports Bank country teams to: mobilize African leaders, civil society and the private sector to intensify action against HIV/AIDS; to retrofit Bank projects with HIV/AIDS components where possible; to assist with the development of new projects; and strengthens the Bank's partnership with UNAIDS and other key agencies, NGOs and other partners;

The U.S. Export-Import Bank, which, in 1999 financed USD 17 billion of exports to hospitals and for medical equipment and pharmaceuticals. Since an assessment of the enormity of the problem, following the AIDS Durban Conference of July 2000, the Bank offered USD 1 billion a year in financing to the sub-Saharan region to build a sustainable, effective infrastructure of health care.

The **NGO Sector**, including Médecins Sans Frontières (MSF), Consumers International (CI), Consumer Project on Technology (CPT), Health Action International (HAI), Transatlantic Consumer Dialogue (TACD), Act Up, International Council of AIDS Service Organizations (ICASO), Critical Path AIDS Project, International AIDS Economic Network (IAEN), Health Gap Coalition, Family Health International, Oxfam and countless other AIDS service and community organizations and coalitions;

Pharmaceutical companies, who have introduced life-saving therapies to treat HIV/AIDS and its associated opportunistic infections, and who have entered into

preferential pricing arrangements with several countries and organizations and established various drug donation programs; and

Governments, who through the United Nations and other international organizations have focused worldwide attention on the HIV/AIDS crisis in sub-Saharan Africa.

Since 1987, the WHO has provided financial support and technical guidance for AIDS activities in more than 150 developing countries around the world. On 31 December 1995 the program was reformed as UNAIDS. To ensure the continuity of its response to HIV/AIDS global needs, WHO established the office of HIV/AIDS and Sexually Transmitted Diseases (ASD). ASD functions to assist UNAIDS in achieving its goals.[10]

In recent years, a series of high-level meetings have focused on the fight against poverty and communicable diseases, including the G8 (Birmingham 1998, Cologne 1999, Okinawa 2000), the EU-US Summit (Queluz 2000), the EU-Africa Summit (Cairo 2000), the African Heads of State meeting (Abuja, March 20000), and the Social Summit in Geneva (June 20000. Each of these meetings has called for international partnerships to take intensified action to address poverty and communicable disease, including HIV.

The United Nations Security Council, under the presidency of the United States in January 2000, also focused on the HIV/AIDS epidemic in Africa, marking the first time that the Security Council has taken up a development issue. The United States recognized that HIV/AIDS had grown beyond a health or social question to become a threat to global security and stability.

On 3 November 2000, the UN General Assembly adopted a resolution to convene a special session of the General Assembly from 25-27 June 2001 to address the problem of HIV/AIDS and to secure a global commitment to combat the epidemic. The special session will focus on HIV/AIDS in Africa, international funding and cooperation, prevention, access to care and treatment and other issues. It requested the Secretary-General to present a comprehensive report describing, among other things, the status and level of national, regional and international response and cooperation.[11]

According to the Panos Institute, a leading international authority on HIV/AIDS, two primary factors prevent widespread access to treatment for AIDS in the developing world: inadequate health services and lack of drugs.[12] Poor infrastructure in those countries hardest hit by the AIDS epidemic is evidenced by inadequate health facilities, lack of hospital beds and laboratories, lack of trained medical and laboratory staff and non-existent or incomplete drug distribution systems. The Panos

[10] WHO and HIV/AIDS at www.who.int..
[11] "General Assembly Will Convene HIV/AIDS Special Session 25-27 June 2001 to Secure 'Global Commitment' to Combat Epidemic", UN Press Release GA/9809 (at www.un.org/news/press).
[12] "Beyond Our Means? The Cost of Treating HIV/AIDS in the Developing World", Martin Foreman, The Panos Institute (London, 2000) at p. 13 (at www.panos.org.uk).

Institute notes that in Western Europe and North America, public health expenditures upwards of USD 1,500 per person annually are the norm, whereas in Africa such expenditure is frequently under USD 20 per person.[13] Furthermore, 50 percent of the population in sub-Saharan Africa does not have access to clean water, and 48 percent of children under the age of five are under-nourished.[14] Compounding the problems, according to Panos, is the fact that:

> *"[i]n many parts of the developing world, poor administration, lack of funds, cash flow problems and corruption can all prevent even the cheapest treatments from reaching hospitals and patients."*[15]

Debt Relief

An effort to reduce the debt of the poorest countries, the "Highly-Indebted Poor Countries Initiative" (HIPC) launched by the World Bank and International Monetary Fund in 1996, was widely criticized as a failure.[16] In 1999, the lending institutions launched a major expansion of the lending initiative, the HIPC II. According to the World Bank, 11 countries (mostly in Africa) are now receiving relief that will amount to some USD 191 billion over time, and work is progressing to meet the target of debt forgiveness for 20 countries by the end of 2000. The new initiative, the World Bank claims, includes more than twice the relief provided under the original framework, and will cut by more than two-thirds the outstanding debt to more than 30 countries.[17] Critics, however, say that the debt-relief program provides too little relief too late, and will leave the countries as heavily indebted in the end.[18]

Debt relief is important for the reasons more fully set out in the conclusion to this report, which deals in part with financial assistance.

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[13] Ibid.
[14] Ibid.
[15] Ibid. at p. 16.
[16] "Health Care and the Developing World", Pharmaceutical Research and Manufacturers of America, 2000 (at www.phrma.org/publications).
[17] "The HIPC Initiative: Background and Progress Through October 2000", World Bank, 2000 (at www.worldbank.org/hipc).
[18] "Lenders to Speed Up Debt Relief", Mark Drajem, *The Washington Post*, 11 November 2000.

1.2 Focus on Access to Drugs

There are currently three types of antiretroviral drugs (ARVs) approved by the U.S. Food and Drug Administration (FDA) for the treatment of HIV/AIDS: nucleoside reverse transcriptase inhibitors (e.g., AZT, ddI, ddC, 3TC, and d4T); non-nucleoside reverse transcriptase inhibitors (e.g., nevirapine and rescriptor); and protease inhibitors (saquinavir, ritonavir, indinavir, and nelfinavir). The ideal treatment strategy in developed countries involves the use of at least three of these drugs in combination, in a so-called "cocktail" of drugs, that includes a protease inhibitor or non-nucleoside reverse transcriptase inhibitor. Since FDA approval of the first protease inhibitor in 1996, use of the ARV drug cocktail in developed countries has brought impressive results. Mortality rates from HIV/AIDS have been reduced by 75 percent over three years, for example, in the United States.[19]

Despite the remarkable results achieved by the use of these drugs in developed countries, the vast majority of HIV-infected individuals live in developing countries and do not have access to them. Several factors contribute to the lack of access to affordable medicines in sub-Saharan Africa, including infrastructure problems (logistical supply and storage problems); ability to administer and monitor complex and potentially toxic drug regimens, including laboratory testing, patient follow-up and treatment of drug side effects; financing and affordability.

According to the World Health Organization:

- 50 percent of the population in developing countries lack access to essential drugs;

- 50-90 percent of drugs in developing and transitional economies are paid for out-of-pocket, placing the heaviest burden on the poor;

- Up to 75 percent of antibiotics are prescribed inappropriately, even in teaching hospitals in developing countries;

- The worldwide average of patients who take their medicines correctly is 50 percent;

- Antimicrobial resistance is growing for most major infectious diseases;

- Less than one in three developing countries have fully functioning drug regulatory authorities; and

- 10-20 percent of sampled drugs fail quality control tests in many developing countries, often resulting in toxic, sometimes lethal products.[20]

[19] "Progress and Problems in the Fight Against AIDS", B. Hirschel and P. Francioli, *New England Journal of Medicine* 338(13) (1998), pp. 906-908.
[20] WHO Essential Drugs and Medicines Policy (at www.who.int/medicines).

The international community has addressed the issue of access to affordable medicines in numerous settings.

In April of 1999, The **UN Commission on Human Rights** urged member states to promote "improved access to high-quality goods and services for preventing transmission of the virus, and promote effective programs for the care and support of persons infected and affected by HIV, including **through improved and equitable access to safe and effective medication** for the treatment of HIV infection and HIV/AIDS-related illnesses." (our emphasis)[21]

On 24 May 1999 the **World Health Assembly** unanimously adopted a resolution on Revised Drug Strategy[22], which requested the WHO to intensify its activities in six areas: national drug policies, pharmaceuticals and trade agreements, drug information and drug promotion, drug quality, drug donations and partnerships. The resolution urges countries to ensure that health interests are paramount in the pharmaceutical and health policies. In the area of pharmaceuticals and trade agreements, the resolution strengthens the WHO's mandate to study the effects of international trade agreements on health, and to advise member countries on international trade issues within the framework of national drug policies and regulatory measures. The resolution urged states to "explore and review their options under international agreements, including trade agreements, to safeguard access to essential drugs."[23] The WHO had already published information for countries that are reviewing their patent legislation under an earlier mandate from 1996.[24]

At the Third WTO Ministerial Conference in Seattle from 30 November through 3 December, 1999, the **UNAIDS** Secretariat issued a statement supporting the following: preferential pricing of HIV/AIDS drugs so that they are priced affordably at levels consistent with local purchasing power; reduction or elimination of import duties, customs and taxes on HIV/AIDS pharmaceutical products; measures to promote generic competition and the "early working" of patented drugs so that generic drugs can be made available more rapidly; and recourse to compulsory licensing permitted under the TRIPS Agreement in countries where HIV/AIDS constitutes a national emergency.[25] This statement also expressed support for patent protection as an incentive for innovative R&D of new HIV/AIDS drugs and, hopefully, HIV vaccines, but noted that intellectual property rights must be

[21] Commission on Human Rights, Fifty-fifth session, April 21, 1999, E/CN.4/1999/L.72, p.4, para 4.
[22] World Health Assembly, Resolution EB103/1999/R1, Revised Drug Strategy, May 24, 1999.
[23] Ibid.
[24] "Globalization and Access to Drugs: Perspectives on the WTO/TRIPS Agreement, Health Economics and Drugs DAP series No. 7 Revised, World Health Organization, Geneva, 1999, was published to partially respond to the resolution adopted in May 1996 by the 49th World Health Assembly that requested the WHO Director General to "report on the impact of the work of the WTO with respect to national drug policies and essential drugs."
[25] Statement of the Joint United Nations Programme on HIV/AIDS (UNAIDS) at the Third WTO Ministerial Conference, Seattle, 30 November – 3 December 1999, p. 2.

considered in the context of other social interests, such as the human rights concerning health and the benefits of scientific progress and its applications.[26]

In November 1997 UNAIDS initiated the pilot phase of its HIV Drug Access (DAI) to see if it could, working in conjunction with drug companies and four developing country governments, enable those countries to treat a greater number of their HIV-infected people. The African countries selected were Uganda and Ivory Coast, which are currently treating about 900 and 600 patients, respectively. Pharmaceutical partners included Bristol-Myers Squibb, DuPont, Glaxo Wellcome, Hoffmann-LaRoche, Merck, Organon Teknika and Virco. Each country established a national HIV drug policy oversight committee and a variety of programs to educate health care workers and patients about treatment and to provide ancillary care.

According to the UNAIDS evaluation of the DAI, among the lessons learned from the program were:

> *"The DAI has demonstrated that rational use of antiretrovirals is feasible in developing countries within an institutional framework that may be accommodated according to the specificities of the country…The DAI clearly increased capacity in the area of care and support for PLWAs* (People Living with AIDS) *in the four countries. There is an increased knowledge of the use of antiretrovirals by the health care workers as well as a successful transfer of know-how for a comprehensive follow-up of those PLWAs on antiretroviral therapy. There is also an improvement in the distribution and stock management of drugs, the regulation of supply and the ability to regulate the market…In the fields of price reduction of drugs, the Initiative has been a continuing learning experience. This has finally led to a mixed model of price reduction mechanism combining negotiations and competition, which appears as a model that can work in several countries. The DAI clearly shows that open competition including generics is an element of price reduction"*[27].

In stating what should be reinforced or done differently, UNAIDS says it should, among other things, do the following:

> *"(a) Strengthen the 'hook' effect of antiretrovirals for wider access to care in general; Until mid 1999, the DAI focused almost exclusively on making antiretrovirals available, and insufficiently emphasized performance in voluntary counseling and testing, psychosocial support, management of opportunistic infections and palliative [pain-relieving] care.*[28]

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[26] Id at p.2, citing the International Covenant on Economic, Social and Cultural Rights, Articles 12 and 15.

[27] UNAIDS Best Practice Digest, "UNAIDS HIV Drug Access Initiative: Pilot Phase", May 2000 (available at www.unaids.org/bestpractice/digest/files/drugaccess.html)

[28] Ibid.

In its June 2000 Report on the Global HIV/AIDS Epidemic, UNAIDS noted that:

> *"Making drugs more accessible requires a broad look at the underlying reasons for poor access. One factor is the cost of drugs. Another is inadequate information about the drugs needed to manage HIV-related illnesses. Finally, drug access is hampered by the poor capacity of health systems in developing countries to select and use drugs in a rational manner, to monitor patients' progress and side effects, and to manage their drug supply. This is linked in turn to inadequate financing of the health system in general and of the drug supply in particular."*
>
> *"In the current context, attention has mainly focused on drug prices, and in particular the price of antiretroviral drugs still under patent in high-income countries, which makes them financially inaccessible to most people with HIV. However, for reasons mentioned above, people with HIV also have inadequate access to the "essential drugs" for treating HIV-related illness, including drugs that are no longer under patent. The poor availability of drugs for pain relief or respirator distress and for treatment of many HIV-related diseases found in a survey of university teaching hospitals shows how inadequate this access is, even at the highest echelon of the health system."*[29]

In its June 2000 Report on the Global HIV/AIDS Epidemic, UNAIDS outlines steps being taken to address the broad issue of access to drugs:

> *"Through collaboration between the UNAIDS Secretariat, WHO and UNICEF, some of the obstacles to essential drug access are being tackled. First, beginning in 1997, 15 new drugs of interest to people with HIV were included in the WHO Model List of Essential Drugs. The next step was to pinpoint the reason why most wholesalers of generic drugs were not distributing the newly included drugs, and why even several important older drugs were rarely on offer. Working with WHO and UNICEF, the Secretariat identified the manufacturers and prices of 44 essential drugs whose procurement was being hampered by insufficient information on cost and availability. This information has been posted on the UNAIDS, UNICEF and WHO websites along with an offer to assist countries in locating generic drug suppliers and organizing drug procurement."*[30]

[29] Report on the Global HIV/AIDS Epidemic at p. 99.
[30] Report on the Global HIV/AIDS Epidemic at p. 99-100.

More recently, UNAIDS, together with UNICEF, WHO, UNFPA and the World Bank have been inviting expressions of interest from manufacturers of antiretroviral HIV/AIDS drugs, among other drugs, that are committed to providing the products at preferential prices to developing countries.[31] These UN programs and agencies are interested in promoting cooperation with interested parties who will:

- accelerate sustained access to and use of good quality interventions for the treatment of HIV/AIDS-related illnesses and the prevention of mother-to-child transmission of HIV;

- ensure that care and treatment reach significantly greater numbers of people in need; and

- implement programs in ways that respond to the specific needs and requests of individual countries.

In evaluating the expressions of interest, due by 1 December 2000, only those manufacturers "that can supply appropriate products of assured quality and compliance with applicable regulatory and intellectual property laws will be considered."[32]

The question of intellectual property rights and its relation to access to medicines, then, is a crucial part of the picture in efforts to enhance access to essential medicines.

[31] "WHO Expression of Interest" at www.who.int/home/unaids/expression_of_interest.html.
[32] Ibid.

1.3 Change in U.S. and EU Patent Policies

In conjunction with the focus on the cost of HIV/AIDS drugs, there has been a heightened awareness of the role that patents play in driving up drug prices. AIDS and health activists contend that patents and the TRIPS Agreement have the effect of denying access to HIV/AIDS drugs. The drug companies contend that patent protection is essential to provide a return on their R&D investment and to encourage the development of new drugs. In furtherance of this view, drug companies have fiercely defended their patent rights and generally opposed any efforts by governments to permit parallel imports or issue compulsory licenses.

Until recently, the pharmaceutical industry was supported in its efforts by the U.S. government, which had consistently opposed compulsory licensing and parallel importation of drugs under patent in other countries. The U.S. government viewed compulsory licensing as a threat to patent incentives that encourage innovation and it viewed parallel importation as a threat to the cost structures adopted by the pharmaceutical industry. The European Union had expressed similar views.

The U.S. government pressured South Africa and Thailand not to permit compulsory licensing or parallel imports. In the case of South Africa, one of the few sub-Saharan African countries where pharmaceutical companies have patents in force, the government had passed the Medicines and Related Substances Control Act, Act No. 90 of 1997 ("the Act") which allowed parallel imports (section 15C) and local South African companies to produce HIV/AIDS drugs under compulsory license (Section 22C).

Section 15C of the Act provides:

> *"The Minister [of Health] may prescribe conditions for the supply of more affordable medicines in certain circumstances so as to protect the health of the public, and in particular may-*
> *…*
>
> *(b) prescribe the conditions on which any medicine which is identical in composition, meets the same quality standard and is intended to have the same proprietary name as that of another medicine already registered in the Republic [of South Africa], but which is imported by a person other than the person who is the holder of the registration certificate of the medicine already registered and which originates from any site of manufacture of the original manufacturer as approved by the council in the prescribed manner may be imported."*

Section 22C provides in part:

> *"(1) Subject to the provisions of this section –*

(b) the council may, on application in the prescribed manner and on payment of the prescribed fee, issue to a manufacturer, wholesaler or distributor of a medicine or medical device a license to manufacture or act as a wholesaler of or distribute, as the case may be, such medicine or medical device, upon such conditions as to the application of such acceptable quality assurance principles and good manufacturing and distribution practices as the council may determine."

As a result of the Act and what was perceived as a threat to international patent laws, South Africa was placed on the "watch list" under "Special 301" of the U.S. trade laws on 30 April 1999.[33] The South African government argued that the WTO TRIPS Agreement expressly permits the granting of compulsory licensing and parallel importation. Nevertheless, the U.S. government pressured the South Africans to repeal the Act.

The argument, on the part of the South African Government, that the Act does not contravene the provisions of the TRIPS Agreement, has not yet been settled in law.[34] It is necessary, however, to discuss some aspects of the debate here since it touches on the view expressed in this paper, that the TRIPS Agreement is in fact flexible. Whether or not it can be successfully argued that Article 8 and Article 73 allow a government to flout the provisions of TRIPS when adopting measures that *inter alia* have the effect of protecting public health and taking action necessary for the protection of its essential security interests has not been decided. Article 8 specifically provides that such measures should be consistent with TRIPS. The relevant sections of the Act, if ever examined in a court of law, may or may not prove to be consistent with TRIPS.

It has not been necessary to test the view taken by the South African government, however, since a softening of the U.S. position emerged, apparently resulting from growing pressure from activists both in the United States and South Africa.

Interesting to note, however, is that the South African patent law has always provided for compulsory licensing and that prior to the enactment of the Medicines and Related Substances Control Act, the Patents Act was not attacked on this basis.[35]

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[33] The "Special 301" provisions of the Trade Act of 1974, as amended, require the USTR to identify foreign countries that deny adequate and effective protection of intellectual property rights or fair and equitable market access for U.S. persons that rely on intellectual property protection. Special 301 was amended in the Uruguay Round Agreements Act to clarify that a country can be found to deny adequate and effective intellectual property protection even if it is in compliance with its obligations under the TRIPS Agreement.

[34] A case brought against the South African Government on the basis of its enactment of the Medicines and Related Substances Control Act, 90 of 1997 by the Pharmaceutical Manufacturer's Association of South Africa has been settled, without a judgment finding for or against the government's view.

[35] The Patents Act, No 57 of 1978 (as amended) provides for compulsory licensing in cases of abuse of patent rights and for dependent patents. Patent rights are deemed abused, are among other things

Coalitions of organizations including Médecins Sans Frontières, Consumers International, Consumer Project on Technology, Health Action International, Transatlantic Consumer Dialogue (TACD) and Act Up! engaged in campaigns in both the United States and South Africa against the pressure being brought to bear on the South African government. The Congressional Black Caucus in the United States also pushed legislation that would prevent the United States from continuing to pressure the South African government. Chronologies of these activities can be found on the web sites of these organizations at (www.msf.org, www.cpt.org, etc.).

On 17 September 1999, officials of the United States and South Africa reached a common understanding on the issue of intellectual property rights as they pertain to the pharmaceutical industry. The understanding was premised on the commitment of both governments to the TRIPS Agreement, as well as an appreciation of the South African government's efforts to provide affordable health care to its people in a national emergency. This understanding recognized that the TRIPS Agreement was designed to ensure high levels of intellectual property protection while enabling governments to address national social needs. This sentiment is enshrined in Articles 31 and 6 of the TRIPS Agreement, discussed more fully below.

The U.S. policy shift, i.e. that South Africa was in contravention of the TRIPS Agreement and should thus be sanctioned, was more broadly made known at the Third Ministerial Conference of the World Trade Organization in Seattle in December 1999. President Clinton announced at the meeting that the United States was committed to helping developing countries gain access to affordable medicines, including those for HIV/AIDS, and that, as a result, the United States would ensure the application of U.S. trade law related to intellectual property remain sufficiently flexible to respond to public health crises. Vice President Gore reiterated this message in his January 2000 speech at the United Nations Security Council.

In response to a reporter's question at a press briefing in Seattle, Ambassador Charlene Barshefsky, the U.S. Trade Representative, explained the policy:

> *The President,* [as you know, in his speech yesterday] *did announce that the protection of intellectual property rights is obviously critical and is the foundation of a modern economy. He also said, however, that in the case of a health crisis, particularly the issue of HIV-AIDS, that U.S. intellectual property rights policy, while consistent with the intellectual property agreements of the WTO, would be administered in a manner flexible enough to ensure affordable medicines for the poorest countries*

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where the invention is not being worked in South Africa on a commercial scale or where demand for the patented article is not being met to an adequate extent and on reasonable terms.

> *If a country comes to us and indicates that there is a health crisis or health emergency, particularly in respect of HIV-AIDS, we would consult with the Department of Health and Human Services…. We would then be informed of that series of discussions and would take action which we believe would appropriately protect intellectual property rights but provide for the ability of the country at issue to ensure that adequate and effective medications would be available in a cost-effective manner."*[36]

In furtherance of this stance and the intergovernmental discussions with the South African Government, the United States on 27 January 2000 gave Thailand permission to issue compulsory licenses for HIV/AIDS drugs under patent in Thailand. In a letter to the chairman of the PHA Network of Thailand, the Assistant U.S. Trade Representative for Services, Investment and Intellectual Property wrote:

> *"We encourage Thai officials to explore all options for extending access to effective treatments, including ongoing direct dialogue with pharmaceutical manufacturers. But the final choice is one for Thailand to make. If the Thai government determines that issuing a compulsory license is required to address its health crisis, the United States will raise no objection, provided the compulsory license is issued in a manner fully consistent with the WTO Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS)."*[37]

On 10 May 2000, U.S. President Bill Clinton issued Executive Order 13155, "Access to HIV/AIDS Pharmaceuticals and Medical Technologies".

It is worthwhile to cite a portion of the text:

> *"In administering sections 301-310 of the Trade Act of 1974, the United States shall not seek, through negotiation or otherwise, the revocation or revision of any intellectual property law or policy of a beneficiary sub-Saharan Africa country, as determined by the President, that regulates HIV/AIDS pharmaceuticals or medical technologies if the law or policy of the country:*
>
> *1) Promotes access to HIV/AIDS pharmaceuticals or medical technologies for affected populations in that country; and*
>
> *2) Provides adequate and effective intellectual property consistent with the Agreement on Trade-Related*

[36] Press Briefing at WTO Ministerial Conference, 2 December 1999 (at www.ustr.gov/speech-test).
[37] Letter from Joseph S. Papovich to Mr. Paisan Tan-Ud of January 27, 2000, available on the web site of Consumer Project on Technology, www.cptech.org, under ip/health/aids. MSF reports that ddI is now being produced in Thailand in powder form, but not under compulsory license since this form is not covered by patent. See MSF Dossier 3, July 2000 at www.accessmed-msf.org.

> *Aspects of Intellectual Property Rights (TRIPS Agreement) referred to in section 101 (d) (15) of the Uruguay Round Agreements Act (19 U.S.C 3511 (d) (15).*[38]

It is clear from what is set out above that it has not been settled as to whether South Africa's Medicines and Related Substances Control Act in fact satisfies the second requirement of the order. However, it is also clear that the U.S. government is prepared to condone what might previously have been considered to be a flouting of the TRIPS Agreement for the policy reasons set out in the order.

The Executive Order further directs the U.S. government to encourage all beneficiary sub-Saharan African countries to implement policies designed to address the underlying causes of the HIV/AIDS crisis by, among other things, encouraging prevention of infection, developing the infrastructure to deliver adequate health services, and providing incentives for research and development of vaccines and other medical innovations to combat the HIV/AIDS epidemic in Africa.

The European Union similarly shifted its position with regard to compulsory licensing and parallel importation in recent months. It had previously joined the United States in pressuring South Africa. The shift was noticeable at the UN General Assembly Special Session (UNGASS) on Social Development in July 2000, where the EU tabled a text pointing out the inherent flexibility of the TRIPS Agreement, which could be used by developing countries to improve access to drugs.[39] The U.S. and EU objected to a proposal by South Africa that read in part: "intellectual property rights under the WTO-TRIPS Agreement should not take precedence over the fundamental human right to the highest attainable standard of health care … and the ethical responsibility to provide life saving medications at affordable cost to developing countries and people living in poverty."[40] The final text agreed to at the UNGASS includes the following:

> *"countries may freely exercise, consistent with national laws and international agreements acceded to, in an unrestricted manner, the options available to them under international agreements to protect and advance access to life-saving and essential medicines."*[41]

In September 2000, speaking in Brussels at a Round Table on Communicable Diseases cosponsored by the European Commission, the WHO and UNAIDS, European Trade Commissioner Pascal Lamy stated:

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[38] Public Law 103-465, 108 Stat. 4809

[39] Cecilia Oh, "Patents versus Affordable Medicines at Geneva 2000", Third World Network, 8 July 2000 (available on the web site of Health Action International at www.haiweb.org/news/summit.summary.html).

[40] Ibid.

[41] Ibid.

> *"In the trade area, I am committed to do whatever is necessary in order to shape the right conditions so that the poorest of the poor will have access to the medicines they deserve at affordable prices…*
>
> *"We are aware that consumer prices vary widely, within and amongst countries for a variety of reasons, such as differences in demand, purchasing capacity, tariffs, intellectual property rights, pricing mechanisms and the degree of competition between patented and generic medicines…*
>
> *"In the area of intellectual property rights, it is acknowledged that TRIPS provides for the necessary flexibility to address public health concerns and emergency situations. It is not a question of encouraging – or indeed discouraging – compulsory licensing. If the conditions of Article 31 of the TRIPS Agreement are fulfilled, the authorities can use this provision."*[42]

In the "Communication of the Commission to the Council and the European Parliament", the Commission acknowledged that countries can use the flexibility within the TRIPS Agreement to grant compulsory licenses to address public health concerns.[43] According to several commentators, including MSF,

> *"[t]his is a radical shift. In November 1999, an official of DG trade stated at a public meeting that patents had nothing to do with the access crisis and should not be used as a mechanism to address this issue."*[44]

It should be noted that the Commission also advocates that industry used tiered pricing, together with effective measures to prevent parallel trading to higher price developed countries; voluntary licensing agreements, and cooperation between the generic and R&D based pharmaceutical industries[45].

[42] EU Press Release "Commissioner Lamy pledges action on access to medicines", Brussels, 28 September 2000 (available on the EC web site at http://europa.eu.int/comm/trade/whats_new/medic.html.
[43] Communication of the Commission to the Council of the European Parliament, "Accelerated action targeted at major communicable diseases within the context of poverty reduction", COM (2000) 585 final, Brussels, 20 September 2000, p. 20.
[44] Mèdecins San Frontiéres Press Release, "Commission Looks at Link Between Patents and Prices of Life-Saving Drugs in Poor Countries", Brussels, 28 September 2000.
[45] Ibid. at 19-20.

1.4 Compulsory Licensing, Parallel Imports and Generic Production

Following the softening of U.S. and EU opposition to compulsory licensing and parallel importation, the drug companies began advancing offers of reduced pricing. In May 2000, as a result of growing pressure on the pharmaceutical industry from the public organizations concerned with the AIDS crisis and access to HIV/AIDS drugs, five companies including Bristol-Myers Squibb, Merck & Co, Glaxo Wellcome, Roche, and Boehringer Ingelheim agreed with officials of UNAIDS and the World Bank to sell their drugs in sub-Saharan Africa at greatly reduced prices. However, a deal was not struck with an African country to secure the discounted drugs until October 2000.[46] Senegal has negotiated a reduced price with Bristol-Myers for Zerit and Videx (d4T and ddI) taken together for $1.60 per day, or $584 per year, far below the cost in the U.S.[47]

Even at the greatly reduced prices, however, the drugs still remain too high for most people suffering from HIV/AIDS. The reader is referred to the country profiles annexed, which set out the average GDP figures. These figures make it clear that affordability is a key issue and that the initiative of the pharmaceutical companies may not address the enormous problems facing the poorest populations where HIV/AIDS has become an endemic crisis of the greatest magnitude.

The Joint United Nations Program on HIV/AIDS (UNAIDS) estimates that more than USD 2 billion in annual global investment is necessary. Yet only USD 300 million has been invested in the effort this year.

Over the past months, a growing chorus of commentators added their voices to the call for more affordable drugs. As stated in a New York Times editorial:

> *"In recent months, pharmaceutical companies, the World Bank, governments and foundations have promised donations of drugs or new money, in some cases hundreds of millions of dollars' worth. Donated drugs are important, but South Africa is proposing a more sustainable solution – making cheap versions of still-patented drugs or importing them at less than the makers charge. These steps were blocked by Washington – which has since changed its view – and the pharmaceutical industry. Wealthy countries should support South Africa, and help all of Africa to get drugs at the lowest possible prices."* [48]

Notwithstanding the view expressed by the *New York Times*, it is not at all clear whether attempts to abrogate patent protection through compulsory licensing and parallel importation will ultimately result in better access to medicines and healthcare. The evidence from the information collected by IIPI from the

[46] World Bank Press Release, "Senegal Secures Price Reductions for HIV Drugs", October 24, 2000.
[47] Ibid.
[48] "AIDS in South Africa", Editorial, The New York Times, July 12, 2000.

pharmaceutical companies, ARIPO, OAPI and sub-Saharan countries, dealt with in greater detail below, suggests that in countries where the drugs are not patented, there is still poor access to pharmaceuticals.

Nonetheless, some have called for the generic production of HIV/AIDS drugs, citing Brazil as an example.[49] 1997 marked the start of Brazil's controversial policy of producing HIV/AIDS drugs and the distribution thereof to patients, free of charge. Two decades ago, when the first cases of AIDS emerged in Brazil, health experts forecast that by now the HIV virus would afflict at least 1.2 million Brazilians. Instead infection rates have returned to 1995 levels.[50] Key to Brazil's success in curtailing the death rate has been its drug distribution campaign and its decision to manufacture generic pharmaceuticals. *The Washington Post* reports that: "Today, government [Brazilian] labs churn out five generic AIDS medications."[51] With the introduction of Brazil's policy of universal access to antiretroviral drugs that, according to UNAIDS, currently benefits nearly all AIDS patients there (about 85,000), the number of AIDS deaths between 1996 and 1999 have been nearly halved, and the incidence of opportunistic infections reduced by 60-80 percent.[52]

Notwithstanding the production of generic pharmaceuticals, which Brazil had the know-how and infrastructure to undertake, it is clear that Brazil's decision to do so accompanied a substantial financial input. The programs' annual drug costs were about USD 339 million in 1999, and are expected to rise to USD 462 million for year 2000 from a larger patient population and a larger proportion of patients on triple combination therapy. According to UNAIDS, the annual cost of double therapy with nucleoside analogues in Brazil decreased on average by 80 percent between 1996 and 2000, from USD 3,812 to USD 763 per patient. For triple therapy with two nucleosides and one protease inhibitor, the cost reduction was 36 percent (from USD 7 342 to USD 4 717), and for triple therapy with two nucleosides and one non-nucleoside, it was 34 percent (from USD 4 584 to USD 3 009).[53] Hence, whether proprietary or generic drugs are used, affordability is a key element in access to HIV/AIDS drugs.

As realistically stated by the advocacy group Project Inform:

> *"The pharmaceutical industry can and must be made to do its part in confronting AIDS, but it would be extremely naïve of us to believe that lower drug prices alone will solve the problem. Blaming industry for the entire problem is a convenient but false solution. There is a huge need for additional funding from the developed nations and the major international private foundations, as well as a sustained and corruption-free effort on the part of nations in need. There is plenty of blame to pass around for having let things get as*

[49] These include MSF, Health Action International, Consumer Project on Technology, for example.
[50] "Brazil becomes Model in Fight against AIDS", Stephen Buckley, The Washington Post, 17 September 2000
[51] Ibid
[52] Report on the Global HIV/AIDS Epidemic at p. 101.
[53] Report on the Global HIV/AIDS Epidemic at p. 102.

bad as they are. AIDS is the world's problem, and until we learn to address it as such, no real progress will be made."[54]

There is also concern that improper use of antiretrovirals will lead to the emergence of mutations and new HIV strains that will be drug resistant. HIV is highly mutable and can develop resistance to a single drug in a matter of days. The experience with tuberculosis is instructive. It has been possible to effectively treat TB for over 50 years, yet it remains a leading killer. A course of treatment for one patient costs as little as USD11.00, yet less than half of those diagnosed complete treatment. The emergence of resistant strains of tuberculosis, related to poor compliance with treatment prescriptions, threatens to make existing drugs ineffective worldwide. TB has increased four-fold in many developing countries and has re-emerged after steady decline in parts of Eastern Europe.[55]

There are also serious concerns about counterfeit and substandard products, as many developing countries do not have the technical, financial or human resources required to monitor the quality of drug products. According to MSN, during the meningitis epidemic in Niger from February to May 1995, about 60,000 people were inoculated with counterfeit vaccines that included no traces of the active effective product.[56] They state:

"MSF teams have encountered many similar field examples that lead to the following conclusions: organized illegal circuits seem more inclined to manufacture copies with the appearance of known trademark drugs (counterfeit), rather than comparatively less expensive generic products; whereas, non-organized illegal circuits (small production) increasingly manufacture drugs whose composition is substandard or inadequate, including generic drugs. Poor quality may be accidental, with no intention to deceive, but oversights in manufacturing or neglected controls may sometimes have tragic consequences. Such was the case during recent decades with acetaminophen syrups which contained, by mistake, a lethal ingredient."[57]

For these and other reasons, the WHO Guidance Module on use of antiretrovirals states that certain essential specific services and facilities must be put in place before considering the introduction of antiretroviral treatment (ART) into any setting. These essential conditions include:

"Assured access to voluntary HIV counseling and testing and the institution of follow- up counseling services for ART to ensure

[54] "Drug Pricing, AIDS and the Developing Nations" at p. 14.
[55] Communication of the Commission to the Council of the European Parliament, p. 9.
[56] "Access to Essential Drugs in Poor Countries: A Lost Battle?", Bernard Pecoul et al., MSF (at www.accessmed-msf.org)
[57] Ibid.

continued psychosocial support and to enhance adherence to treatment;

"Capacity to recognize and appropriately manage common HIV related illnesses and opportunistic infections;

"Reliable laboratory monitoring services including routine hematological and biochemical tests for the detection of drug toxicity as well as access to facilities for monitoring the immunologic and virologic parameters of HIV infection;

"Assurance of an adequate supply of quality drugs, including drugs for the treatment of opportunistic infections and other HIV illnesses;

"Identification of sufficient resources to pay for treatments on a long-term basis;

"Information and training on safe and effective use of antiretroviral drugs for health professionals in a position to prescribe ART; and the

"Establishment of reliable regulatory mechanisms against misuse and misappropriation of antiretroviral drugs".[58]

The need to establish effective infrastructure to administer antiretroviral drug regimens is often overlooked in discussions on the HIV/AIDS crisis in sub-Saharan Africa.[59] Calls to "override patents" and point blame at the TRIPS Agreement for blocking access to medicines are often made without reference to factors such as infrastructure and drug resistance. But just what role do the TRIPS Agreement and patents play in the access to HIV/AIDS drugs? The following chapters explore this question.

[58] WHO Initiative on HIV/AIDS and Sexually Transmitted Infections, "Use of Antiretroviral Treatments in Adults", Geneva 2000.04 (at www.who.int/HIV_AIDS)

[59] "Call For Regional Manufacture of AIDS Drugs", Panafrican News Agency, September 29, 2000 (at http://allafrica.com/stories/200009290299.html).

2. The International Patent Regime

The establishment of the World Trade Organization on 1 January 1995 dramatically changed the landscape with regard to the patenting of drugs. For the first time in the world trading system, countries that belong, or wish to belong, to the world trading system must undertake to abide by comprehensive rules for the protection of intellectual property rights. These rules, set out in the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights ("TRIPS"), set minimum standards for the protection and enforcement of intellectual property rights, including patents, trademarks, copyrights and related rights, geographical indications, industrial designs, layout-designs of integrated circuits and undisclosed information. All WTO members must comply with these standards by giving them effect in their national legislation within the time periods prescribed in the Agreement. Failure of a member to implement its obligations under the TRIPS Agreement can result in a complaint under the WTO dispute settlement system, which can ultimately result in trade sanctions authorized by the WTO against that member. Currently, the WTO has 139 members[60], with almost 30 more candidates lining up for membership.[61]

Prior to the TRIPS Agreement, the Paris Convention for the Protection of Industrial Property, concluded in 1883 and revised several times since then, governed international patent relations. The Paris Convention, however, has not been revised since 1979, and lays down few rules regarding patents. It does not, for example, require that patents be available for any particular areas of technology, nor does it require any minimum term of protection or set of exclusive rights to be conferred on

[60] The following are WTO members as of 1 December 2000: Albania, Angola, Antigua and Barbuda, Argentina, Australia, Austria, Bahrain, Bangladesh, Barbados, Belgium, Belize, Benin, Bolivia, Botswana, Brazil, Brunei Darussub-Saharan Africalam, Bulgaria, Burkina Faso, Burundi, Cameroon, Canada, Central African Republic, Chad, Chile, Colombia, Congo, Costa Rica, Cote d'Ivoire, Cuba, Cyprus, Czech Republic, Democratic Republic of the Congo, Denmark, Djibouti, Dominica, Dominican Republic, Ecuador, Egypt, El Salvador, Estonia, European Communities, Fiji, France, Gabon, The Gambia, Georgia, Germany, Ghana, Greece, Grenada, Guatemala, Guinea Bisub-Saharan Africau, Guinea, Guyana, Haiti, Honduras, Hong Kong, Hungary, Iceland, India, Indonesia, Ireland, Israel, Italy, Jamaica, Jordan, Japan, Kenya, Republic of Korea, Kuwait, The Kyrgyz Republic, Latvia, Lesotho, Liechtenstein, Luxembourg, Macau, Madagascar, Malawi, Malaysia, Maldives, Mali, Malta, Mauritania, Mauritius, Mexico, Mongolia, Morocco, Mozambique, Myanmar, Namibia, Netherlands, New Zealand, Nicaragua, Niger, Nigeria, Norway, Pakistan, Panama, Papua New Guinea, Paraguay, Peru, Philippines, Poland, Portugal, Qatar, Romania, Rwanda, Saint Kitts and Nevis, Saint Lucia, Saint Vincent & the Grenadines, Senegal, Sierra Leone, Singapore, Slovak Republic, Slovenia, Solomon Islands, South Africa, Spain, Sri Lanka, Suriname, Swaziland, Sweden, Switzerland, Tanzania, Thailand, Togo, Trinidad and Tobago, Tunisia, Turkey, Uganda, United Arab Emirates, United Kingdom, United States, Uruguay, Venezuela, Zambia and Zimbabwe.

[61] 28 governments are currently negotiating accession to the WTO: Algeria, Andorra, Armenia, Azerbaijan, Belarus, Bhutan, Bosnia and Herzogovina, Cambodia, Cape Verde, People's Republic of China, Former Yugoslav Republic of Macedonia, Kazakstan, Lao People's Democratic Republic, Lebanon, Moldova, Nepal, Russian Federation, Samoa, Saudi Arabia, Seychelles, Sudan, Chinese Taipei, Tonga, Ukraine, Uzbekistan, Vanuatu, Vietnam and Yemen. Lithuania completed accession negotiations on 2 October 2000 and the WTO's General Council is due to approve the accession in December.

patent holders. Several countries, therefore, excluded pharmaceutical products as being eligible for patent protection, and had widely divergent terms for patents.

The developed countries, in seeking to provide the necessary incentives for drug innovation, successfully negotiated the mandatory protection of pharmaceutical products, as well as processes in the TRIPS Agreement (with exceptions, limitations and transition periods, discussed below). Given the high cost of developing new drugs, and their low costs of reproduction, they are deemed especially worthy of patent protection by the developed countries. By giving limited exclusive rights to the innovator in exchange for disclosure of new innovations, governments must balance the competing goals of encouraging innovation and benefiting society. As outlined in this chapter, the TRIPS Agreement does just that by including obligations regarding protection, flexibility in their implementation, and permissible exceptions and limitations on rights.

There are, of course, several reasons for the high costs of medicines. To discover, develop, test and achieve regulatory approval is expensive.[62] Considerable time is taken to establish whether a drug is safe and in consequence only a few drugs sell at a price that meets or exceeds the costs of research and development of the drug.

Clearly the debate centers around how to reach a balance between meeting the high costs of drug research and development and creating incentives to stimulate access to those drugs in poor and developing countries.

[62] From Pharmaceutical Research and Manufacturers of America (Phrma) brochure available at www.phrma.org/publications.

2.1 TRIPS Obligations Regarding Patents

The TRIPS Agreement requires member states to make patent protection available for:

> *"any inventions, whether products or processes, in all fields of technology, provided they are new, involve an inventive step and are capable of industrial application."* (Article 27(1))

While Article 27 of the TRIPS Agreement does permit certain limited exceptions (not particularly relevant here), it also provides that:

> *"[P]atents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced."* (Article 27(1))

These provisions thus require member states to provide patent protection for pharmaceutical products, as well as processes. Patents must be granted for a term of at least 20 years from the application filing date (Article 33). Patents must confer on their owners the exclusive rights to prevent third parties without consent from making, using, offering for sale, selling, or importing covered products (Article 28). These rights, however, may be limited to some extent, as noted in the next section.

Finally, it is important to note the requirements of Article 39 ("Protection of Undisclosed Information"), which state in part:

> *"3. Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use."*

This provision requires WTO members to protect health registration data from disclosure or unfair commercial use, but its exact boundaries of "unfair commercial use" are not entirely clear. In the United States, such data must be protected for five years, while in the European Union, the period of data exclusivity is 10 years. Similarly, the parameters of "necessary to protect the public" are unclear.

2.2 TRIPS Provisions for Flexibility

In addition to the obligations regarding patent protection described above, the TRIPS Agreement includes several provisions that may provide flexibility in implementing and interpreting the provisions mentioned above relating to protection of pharmaceutical products.

Article 1 which outlines the nature and scope of obligations provides that:

> *"[m]embers may, but **shall not be obliged to**, implement in their law more extensive protection than is required by this Agreement, ..."*

Several governments and NGO's have cited this provision in opposing efforts by some countries to seek protection beyond that mandated by the TRIPS Agreement.

Article 7 which sets out the objectives of the Agreement provides:

> *"The protection and enforcement of intellectual property rights should contribute to … the mutual advantage of producers and users of technological knowledge and **in a manner conductive to social and economic welfare**, and to a balance of rights and obligations."* (our emphasis).

This provision recognizes that intellectual property protection is not an end by itself, but should be balanced to benefit society as a whole.

Article 8 which sets forth the principles of the Agreement provides:

> *"1. Members may, in formulating their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.*
>
> *2. Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology."*

These provisions recognize that additional measures may be needed to achieve the desired balance between intellectual property protection and larger societal goals. They do require, however, that such measures be consistent with the TRIPS Agreement.

Article 73 which deals with the security exception states:

> *"Nothing in this Agreement shall be construed: … (b) to prevent a Member from taking any action which it considers necessary for the protection of its essential security interests; (iii) taken in time of war or other emergency in international relations; or (c) to prevent a Member from taking any action in pursuance of its obligations under the United Nations Charter for the maintenance of international peace and security."*

This provision permits action that would otherwise contravene the TRIPS Agreement, but only in very limited circumstances: in time of war or "other emergency in international relations" or in pursuance of its UN Charter obligations "for the maintenance of peace and security".

While these provisions must be borne in mind when interpreting the TRIPS Agreement, they do not fundamentally alter the obligations under the Agreement. The WTO Dispute Settlement body, in the case of the EU's complaint against Canada for its exceptions to patent rights for pre-marketing testing and stockpiling of generics, found the pre-marketing testing provision was not inconsistent with the TRIPS Agreement, while the "stockpiling" exception was a violation.[63] In so ruling, the panel noted that while the goals and limitations stated in Articles 7 and 8.1 must be borne in mind. Nevertheless, the panel reasoned, the very existence of Article 30 that permits exceptions to patent rights under specific conditions, outlined below, amounts to a recognition that the definition of patent rights contained in Article 28 might need certain adjustments. The conditions included in Article 30 "testify strongly that the negotiators of the Agreement did not intend Article 30 to bring about what would be tantamount to a renegotiation of the basic balance of the Agreement."[64]

The TRIPS Agreement, more importantly, includes provisions that permit member states to limit patent rights. These include provisions allowing members to legislate certain limited exceptions to rights, to permit parallel imports, and to authorize use of the patented invention without the patent owner's consent, under certain conditions, a practice known as "compulsory licensing", dealt with more fully below.

[63] Canada – Patent Protection of Pharmaceutical Products – Complaint by the European Communities and their member States, Report of the Panel, World Trade Organization, WT/DS114/R, 17 March 2000.
[64] Ibid at p. 154.

2.3 Limited Exceptions to Patent Rights

Article 30 of the TRIPS Agreement permits member states to provide limited exceptions to the exclusive rights conferred by a patent. The article provides that these limitations, however:

> *"must not unreasonably conflict with a normal exploitation of the patent and not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties."*

Although the precise boundaries of permissible exceptions under this provision are not known, they are generally believed to permit experimental uses and non-commercial uses currently practiced in several countries, including the United States.

Of particular interest with regard to access to drugs is the so-called "Bolar" exception to patent rights in the United States that permits pre-marketing testing of generic products during the patent term. The "Bolar" exception to patent rights allows generic manufacturers to conduct tests needed to prepare their applications for regulatory approval during the term of the patent, so that they are then able to market their products immediately upon expiration of the patent.

In the United States, this exception was codified as a compromise between the research-based pharmaceutical industry and the generic industry in 1984, with the enactment of patent term restoration (up to five years to compensate for the loss of patent term caused by required regulatory approvals). As noted above, this exception as applied by Canada was held to be consistent with the TRIPS Agreement by a WTO Dispute Settlement panel, even though Canada's "Bolar" exception was not balanced, as in the U.S., with the possibility of patent term restoration.

2.4 Parallel Importation

The rights conferred by patents enumerated in Article 28 are not absolute. They may be limited by the "exhaustion" doctrine. Article 6 of TRIPS provides that the issue of exhaustion of intellectual property rights is not subject to WTO dispute settlement. A complaint cannot be brought against a member, therefore, if that member adopts a patent regime based on "international exhaustion" and thereby permits parallel imports. Also sometimes known as the "first sale" doctrine, the exhaustion principle allows a member state to limit application of a patent right once a product protected by the patent has been sold.

In the U.S., this doctrine normally applies as a "national exhaustion" principle, meaning that the patent owner can no longer exercise control over the product once it is placed on the domestic market in the United States. The patent owner, however, may exercise his rights with regard to products placed on the market outside of the United States. The European Union countries apply a "regional exhaustion" principle, whereby patent rights are exhausted only with regard to products placed on the market in EU countries.

Many countries apply an "international exhaustion" regime, whereby a patent owner may not exercise rights over products once they have been put on the market anywhere in the world. This limitation on the patent owner's exclusive importation right effectively permits others to import the patented product if it has already been put on the market by the patent owner anywhere in the world. Known as parallel importation, this practice allows for "comparison shopping" among markets where a patent owner sells the product in different markets at different prices. Because the topic of "exhaustion" is not subject to the WTO dispute settlement procedures, a WTO complaint cannot be brought against a member state that adopts a patent regime based on "international exhaustion" and thereby permits parallel imports.

However, to the extent that a country has a drug regulatory system in place and requires test data for marketing approval, it is unclear to what extent parallel importation might run foul of Article 39.3 of the TRIPS Agreement, which requires protection of test data for some period of time.

2.5 Compulsory Licensing

The TRIPS Agreement permits members to use patented inventions without the authorization of the patent owner, either by the government (so-called "government use") or by third parties (so-called "compulsory licensing"), as long as certain procedural conditions are met. The grounds upon which a compulsory license may be granted, or government use authorized, are not restricted by the TRIPS Agreement, except in three areas: non-working and dependent patents (discussed below) and semi-conductor technology (not relevant here). Where the prescribed procedural conditions are followed, compulsory licenses are permitted on any grounds, including public health, national interest, food security, etc.

The most relevant conditions prescribed in Article 31 of the TRIPS Agreement include:

- authorization of use without the consent of the patent owner must be considered on its individual merits;

- efforts to obtain a voluntary license on reasonable terms and conditions must first be made (except for government use, which only requires notification);

- the scope and duration of the use must be limited to the purpose for which it was authorized;

- the use must be non-exclusive;

- the use must be authorized predominantly for the supply of the domestic market of the member authorizing the use;

- the authorization of use can be terminated if and when the circumstances which led to it cease to exist and are unlikely to recur;

- the patent owner must be paid adequate remuneration taking into account the economic value of the authorization; and

- the decisions relating to authorization and remuneration must be subject to judicial review or other independent review by a distinct higher authority in that member.

It should be noted that the requirement to first seek a voluntary license does not apply to government use. This requirement is also waived where a compulsory license is authorized to remedy behavior found to be anti-competitive by judicial or administrative process. In addition, the requirement that the use be predominantly for the domestic market does not apply in such cases, and the "need to correct anti-competitive practices may be taken into account in determining the amount of remuneration".

As mentioned, there are three situations that have additional rules: authorizing use for "non-working" patents, for dependent patents, and for semi-conductor technology. A member may only authorize use of semiconductor technology by third parties to remedy a practice determined to be anti-competitive. A member state may only authorize the use of a dominant patent by the holder of a "dependent" patent if three conditions apply:

(1) the dependent patent represents an important technical advance of considerable economic significance;

(2) the owner of the dominant patent is entitled to a cross-license (to practice the invention of the dependent patent); and

(3) the use authorized is not assignable except with the assignment of the dependent patent.

More relevant to this report is the situation with regard to authorization of use for "non-working" patents, i.e., where a member wishes to grant a license to practice the invention to a third party because the patent owner is not "working" his invention locally. In this situation, two additional conditions apply. First, the Paris Convention places time limits on when such licenses can be granted, and these, along with all substantive provisions of the Paris Convention, are incorporated into Article 2 (1) of the TRIPS Agreement.

Article 5 of the Paris Convention provides, *inter alia,* that countries have the right to take legislative measures providing for the grant of compulsory licenses:

> *"to prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent, for example, failure to work."*

It further provides that a compulsory license may not be applied for on the ground of failure to work or insufficient "working" before the expiration of four years from the date of filing, or three years from the date of grant, whichever expires later, and that the compulsory license shall be refused if the patentee justifies his inaction by legitimate reasons. These conditions imposed on "non-working" compulsory licenses do not apply to compulsory licenses and government use based on other grounds such as public health or national interest.

Another limitation on compulsory licenses or government use for "non-working" patents is imposed by Article 27(1) of the TRIPS Agreement, which states in part:

> *"patents shall be available and patent rights enjoyable* ***without discrimination as to*** *the place of invention, the field of technology and* ***whether products are imported or locally produced.****"* (our emphasis).

This provision would seem to require that importation of products should be deemed to satisfy a local working requirement.

2.6 Transition Periods

Developing countries, countries in transition to market economies, and least developed countries were given longer transition periods to implement the TRIPS Agreement into their national legislation than developed countries. In addition there are special provisions relating to the protection of pharmaceutical products, outlined below.

Developed countries were given one year to bring their legislation into conformity with the TRIPS Agreement and all countries were required to implement the national treatment and most-favored-nation provisions within that time, i.e., by 1 January 1996. Developing country members, and members in the process of transition to a market economy, were given an additional four years to implement the TRIPS Agreement, i.e., until 1 January 2000 (Article 65). Least developed country members were given until 1 January 2006, to implement TRIPS, in view of their special needs and requirements, "their economic, financial and administrative constraints, and their need for flexibility to create a viable technology base." (Article 66(1)). Further, the Council for TRIPS is instructed to accord extensions of this period to least developed country members upon a duly motivated request.

Article 65(4) provides that developing countries that did not extend patent protection to required areas, such as pharmaceutical products, on January 1, 1995, were given a transition period of five years, in addition to the general five-year transition period for developing countries, to introduce such protection. Such developing countries, therefore, have until January 1, 2005, to introduce patent protection for drugs if they did not already have it.

There are a number of transition periods set out in Article 65. These are: one year for developed countries, five years for developing countries and countries in transition and 11 years for new patentable subject matter. The periods must be read, however, in conjunction with the "standstill" clause 5 of Article 65. This clause prohibits members from using the transition periods to change legislation so that the result is a "lesser degree of consistency with the provisions of this Agreement." This provision is meant to preclude countries that already had TRIPS-consistent legislation from revising the legislation in any way that would result in inconsistency with the Agreement during the transition period. It is important to note that clause 65 does not apply to least developed countries.

Finally, Article 70, which deals with protection of existing subject matter, imposes immediate obligations relating to pharmaceutical products on member states that did not have patent protection for such products available on the date of entry into force of the WTO (January 1, 1994). As from that date, Article 70(8)(c) requires that these states must establish a so-called "mail box", or a means to accept patent applications on these products immediately. The reasoning behind the provision is to ensure that, when these states do make patent protection available for pharmaceutical products, the inventions will be examined for novelty as of their "mail box" filing

date, or foreign priority date under the Paris Convention. This provision will permit the patenting of these inventions when protection is introduced because they have not lost their "novelty" due to a late filing date, for example, after publication by another patent office. The term of such patents will run for 20 years from the filing date.

Article 70(9) requires that "mail box" applications filed after January 1, 1994 must also be eligible for "exclusive marketing rights" under certain conditions, notwithstanding the transition periods provided to developing and least developed countries. A "mail box" country must grant exclusive marketing rights to the product of a "mail box" patent application for a period of five years, or until a product patent is granted or rejected by that member, if:

(1) a patent has been granted, and marketing approval obtained, in another WTO member state; and

(2) marketing approval has been granted by the "mail box" country.

This creates an unusual situation under the TRIPS Agreement, i.e. a country that did not have product patent protection for drugs on 1 January 1994, may be required to grant exclusive marketing rights at least until it can grant or reject the patent application. A country that has product patent protection for drugs can reject the application and have no obligation to provide exclusive marketing rights.

Bearing this overall framework in mind the section following explores Sub-Saharan African national and regional legislation and the patent situation of certain HIV/AIDS drugs.

3. The Patent Situation in Sub-Saharan Africa

At the time the TRIPS Agreement entered into force on 1 January 1995, only three countries in continental sub-Saharan Africa excluded pharmaceutical products from patentability: Angola, Ghana, and Malawi.[65] There are substantial differences among sub-Saharan African countries, however, in the particulars of their patent laws, especially with regard to parallel importation and compulsory licensing. This section attempts to provide an outline of the various patent regimes in sub-Saharan Africa, both national and regional.

It also describes efforts by the International Intellectual Property Institute (IIPI) to determine the patent status of the anti-retroviral (ARV) drugs for HIV/AIDS. Despite the possibility of obtaining protection in these most African countries, many pharmaceutical companies have not filed for or obtained patents in the sub-Saharan African countries. The International Intellectual Property Institute has conducted surveys in attempts to determine the patent situation of the anti-retroviral (ARV) drugs for HIV/AIDS. The IIPI sent letters to all of the national patent offices in sub-Saharan Africa and to the drug manufacturers. In addition, letters were sent to the African Regional Industrial Property Office (ARIPO) and the African Industrial Property Office (Organization Africaine de la Propriété Intellectuelle or "OAPI") in an attempt to determine the patent status of these drugs. This section presents the results of the information obtained, together with information gathered from other sources.

This information builds upon earlier work done by UNAIDS with WHO and UNICEF in attempting to determine the patent status of HIV/AIDS medicines in developing countries. According to UNAIDS' analysis, most proprietary drugs used in the treatment of HIV/AIDS are not protected by patents in the majority of developing countries.[66] A drug industry representative, Jeff Sturchio of Merck & Co., who has noted that South Africa is one of the few countries in Africa in which patents are registered, supports this finding. "Why are generic manufacturers not already providing access in these countries, where the patents are not there?" he asks.[67]

The patent status of a drug in a particular country is difficult to ascertain for several reasons. Some drugs are covered by more than one patent, for example, there may be a patent registered for the product, a manufacturing process, and/or a different formulation or use. Most patent offices in the region are not fully automated, and in some cases lack adequate staff to conduct reliable searches of records. Furthermore, most countries require the payment of "maintenance fees" to maintain a patent in

[65] WIPO Document HL/CM/INF/1 Rev. 2 (July 1992).
[66] Report on the Global HIV/AIDS Epidemic at p. 100. See also "Patent Situation of HIV/AIDS-Related Drugs in 80 Countries", P. Boulet, J. Perriens and F. Renaud-Théry, UNAIDS/WHO, Geneva, January 2000.
[67] Belinda Beresford, "Drugs Let the Rich Buy a Few More Years of Life", The Mail & Guardian, 14 July 2000 (at www.mg.co.za/mg/new/2000july1/14Jul-aids2.html).

force once it has been granted, and it is often difficult to determine whether these fees have been paid by the patent owner, and hence, whether a patent, even if granted, remains in force.

For all of these reasons, the International Intellectual Property Institute presents the results of its surveys with the following caveat. The indications of patent status are indicative only, and are based on the responses received by the drug companies and patent offices, which were not complete.

The vast majority of sub-Saharan African countries belong to one of the two regional patent systems that are serviced by the two regional offices for Africa: ARIPO for English-speaking countries and OAPI for French-speaking countries. Each of these regional offices has 15 member countries. The membership of each organization is shown below, as well as the continental sub-Saharan African countries that do not belong to either organization.

ARIPO Members:	**OAPI Members:**	**Other Countries:**
Botswana	Benin	Angola
Gambia	Burkina Faso	Burundi
Ghana	Cameroon	Dem. Republic of Congo
Kenya	Central African Republic	Djibouti
Lesotho	Congo	Equatorial Guinea
Malawi	Ivory Coast	Eritrea
Mozambique	Gabon	Ethiopia
Sierra Leone	Guinea	Liberia
Somalia	Guinea Bissau	Namibia
Sudan	Mali	Nigeria
Swaziland	Mauritania	Rwanda
Tanzania	Niger	South Africa
Uganda	Senegal	
Zambia	Chad	
Zimbabwe	Togo	

All OAPI states are members of the WTO as are all ARIPO states except Somalia and Sudan. Of the countries not belonging to either OAPI or ARIPO, all are WTO members except Equatorial Guinea, Eritrea, Ethiopia, and Liberia.

It is important to note that the following sub-Saharan countries are designated by the United Nations as least developed: Angola, Benin, Burkina Faso, Burundi, Cape Verde, Central African Republic, Chad, Comoros, Democratic Republic of Congo, Djibouti, Equatorial Guinea, Eritrea, Ethiopia, Gambia, Guinea, Lesotho, Liberia, Malawi, Mauritania, Mozambique, Niger, Rwanda, Sierra Leone, Togo, Uganda, Tanzania, and Zambia.[68]

[68] "About LDC's" from http://www.unctad.org/en/subsites/ldcs/aboutldc.htm.

As noted in section 2.6 above, least developed countries are given a transition period of 11 years under the TRIPS Agreement, namely until 1 January 2006, to implement its provisions. Notwithstanding the flexibility afforded to least developed countries by the TRIPS Agreement, the patent laws of many of these least developed countries have already been amended to implement TRIPS, in many cases in conjunction with their membership in a regional system, as more fully set out below. Despite the availability of patent protection for pharmaceutical products, however, few of the HIV/AIDS drugs are patented widely in sub-Saharan Africa.

3.1 ARIPO

The "Industrial Property Organization for English-Speaking Africa" (ESARIPO) was created with the signature of the Lusaka Agreement in 1976. In 1985, this organization was renamed the "African Regional Industrial Property Organization" (ARIPO). Located in Harare, Zimbabwe, ARIPO currently has 15 member states.[69] As mentioned previously, all ARIPO member states, except Somalia and Sudan, are also members of the WTO.

In December 1982, ARIPO adopted the Harare Protocol ("the Protocol"), which empowers the ARIPO office to receive and process patent and industrial design applications on behalf of states party to the Protocol. Currently, all ARIPO members except Somalia have signed the Protocol.

By filing a single application with ARIPO, patent applicants can designate any of the Protocol members in which protection is sought.[70] ARIPO arranges for the substantive examination of the application and makes recommendations to the designated members, who may refuse to grant a patent within six months if the invention is deemed to be unpatentable under the Protocol or under national law. If a member does not refuse the patent within a six-month period, ARIPO grants the patent, which has the same effect as a national patent in each designated state, and is governed by the laws of those states. A reference to the grant is published in the quarterly *ARIPO Journal*, and a copy of the grant certificate and patent are sent to each designated State for which the patent is granted.

Under the Protocol, patents granted by ARIPO were subject to the national law of each designated state with regard to patent term, working requirements, compulsory licenses, and nullification. The Protocol was revised on November 26, 1999, to implement the obligations under the TRIPS Agreement for ARIPO member states. The revised 1999 Protocol established a uniform patent term of 20 years from the application filing date. All but two (Ghana and Malawi) of the ARIPO member states already provided patent protection for pharmaceutical products at that time. The revised version of the Protocol came into force on 1 January 2000, and applies to all ARIPO patents still in force at that time.[71]

3.2 OAPI

[69] ARIPO also has 10 observers who represent potential ARIPO member states: Angola, Egypt, Ethiopia, Liberia, Mauritius, Namibia, Nigeria, Seychelles and South Africa.

[70] Applicants may also use the Patent Cooperation Treaty (PCT) to designate members of the Harare Protocol who are also members of the PCT. Currently 12 ARIPO members are members of both the Protocol and the PCT: the Gambia, Ghana, Kenya, Lesotho, Malawi, Mozambique, Sierra Leone, Sudan, Swaziland, Tanzania, and Zimbabwe.

[71] Ms. Pascale Boulet, Medicins sans Frontieres (MSF), "Patent Protection of Medicines in Kenya and Uguanda", April 2000, Report for discussion at the MSF Conference on "Improving Access to Essential Medicines in East Africa – Patents and Prices in a Global Economy, Nairobi, June 15-16, 2000.

OAPI serves as the regional industrial property office for French-speaking Africa. It succeeds the OAMPI (Office Africain et Malgache de la Propriété Industrielle) which was created by the Libreville Agreement of 1962 to serve as the uniform patent law and the common patent office for each member. Until 1962, French laws governed patent rights in the majority of the member states. The Bangui Agreement of March 2, 1977, revised the Libreville Agreement and created the OAPI, which now has 15 member states, all of which are WTO members.

By filing a single application with OAPI, patent applicants may obtain a patent that covers all 15 OAPI member states. Unlike ARIPO, no designation of individual member states is made.[72] The 1977 Bangui Agreement serves as the national patent law for all OAPI members. Under the Bangui Agreement, which took effect in 1982, the term of patents is 10 years from the application filing date, with the possibility of two extensions of five years each. Application for the first extension must include proof of sufficient working of the patented invention in at least one of the OAPI member states at the time of application for the extension, or legitimate reasons for non-use. Importation of the patented product does not constitute a legitimate reason for not working the invention ("non-working"). Application for the second extension likewise must include proof of working, and legitimate reasons for non-working are not permitted for the second extension.[73]

Once patents are granted by OAPI, they are regulated by the member states, whose courts deal with such issues as infringement and compulsory licenses. Compulsory licenses may be granted by OAPI member states for "non-working" inventions within the time periods established under Article of the Paris Convention and for dependent patents. "Ex officio" licenses also may be granted by OAPI members for inventions of great importance to the national defense, for the public health, or for the national economy where the product cannot be obtained in sufficient quantities on reasonable conditions. The licenses may be granted for importation in cases of inventions of great importance to the national defense or public health.

The 1977 Bangui Agreement does not permit parallel importation, because the patent owner is given the right to exclude imports. However, no action for infringement can be brought if the patent is not sufficiently worked in at least one of the OAPI member states within 5 years from grant (unless there are legitimate reasons for non-working).

The OAPI member states revised the 1977 Bangui Agreement in 1999 to implement the TRIPS Agreement. The revised Bangui Agreement, signed on 24 February 1999 is not yet in force. It would extend the patent term to 20 years from the filing date, add new restrictions on compulsory licensing, and permit parallel imports only from OAPI members. [74] The pending Agreement in many ways establishes the standards

[72] Patent applications filed under the Patent Cooperation Treaty designating OAPI apply only likewise apply to all OAPI member states, since they have each also joined the PCT.
[73] Manual of Industrial Property, …
[74] Pascale Boulet and Gilles-Bernard Forte, "Drug Patents in French Speaking Africa", report of Joint Mission (Medicins Sans Frontieres, UNAIDS & WHO), Cameroon, February 6-10, 2000 (unofficial translation available on the MSF web site, www.msf.org

required under the TRIPS Agreement, although criticism has been leveled at it for creating onerous obligations not mandated by TRIPS.[75] Of the 15 member states of OAPI, only 6, viz. Benin, Burkina Faso, Cameroon, Ivory Coast, Gabon and Senegal are developing countries that were required to implement TRIPS obligations by January 1, 2000.

[75] Ibid.

3.3 Other Sub-Saharan Africa Countries[76]

Angola

Angola was subject to Portuguese law until 1975, when it became an independent state. It had been a Portuguese colony until 1951 and Overseas Province of Portugal until 1975. In 1992, Industrial Property Law No 3/92 of February 28, 1992 was enacted and entered into force on March 29, 1992.

This law, which remains in force, does not permit the patenting of pharmaceutical products, although protection is available for processes and apparatus for the manufacture of such products. The term of patents is 15 years from the date of application filing. Compulsory licenses are available in cases where a patent is not locally exploited within three years from grant, without legitimate excuse for non-working; for the needs of the domestic market have not been met; and where the government believes that exploitation of the patent is of vital importance for the public interest, national security, public health or the economy.

Burundi

Formerly named Urundi, which was part of the Belgian Trust-Territory of Ruanda-Urundi, became independent in 1962. The Patents Act of 1964 and Patent Regulations of 1965, as amended by Decree No. 1/170 of 1968, now govern patent matters in Burundi.

Patents are available for all inventions for a term of 20 years from the application filing date. Patents are granted without examination. There are no provisions for compulsory licenses, but any interested party may bring a court action for cancellation of a patent if the invention is not exploited in Burundi within two years from the date of first commercial working abroad.

Democratic Republic of the Congo

The former Belgian Congo became an independent state in 1960. Patents are governed by Law No. 82-01 of 1982 and by Ordinance No. 89-173 of August 1989, implementing the law.

Patents are available for 20 years from the application filing date, but inventions relating to a medicine may only be patented if the subject matter is a product, substance or compound for the first time presented as constituting a medicine. In other words, new uses and formulations are not patentable. The law includes a

[76] The source for information on the countries in this section is the *Manual of Industrial Property B.V.*, Utrecht, The Netherlands, May 2000 (ISBN 90 7188 01 0).

requirement for local working within five years from the application filing or three years from patent grant, whichever is later, or a compulsory license may be granted for non-working if certain conditions are met. After two years from the grant of the first compulsory license, the Patent Office may bring an action for forfeiture of the patent for non-working or insufficient working.

An applicant for a compulsory license must provide evidence that he or she has first tried to obtain a voluntary license from the patentee, and must prove that he or she has the means for working the patented invention in such a way that the needs of the market may be met.

The Patent Office may grant an ex officio license for working of a patent by the State or a third party on its behalf in cases where non-working or insufficient working would prejudice the economic development of the country in particular and the public interest in general.

Djibouti

The Republic of Djibouti became an independent country in 1977, following administration by France as the Territory of the Afars and Issas (formerly French Somaliland). There is no patent law at present, but prior to independence, patent rights acquired in France extended to the former Territory. As a least developed country WTO member, Djibouti has until at least 2006 to implement the TRIPS Agreement.

Equatorial Guinea

The former Spanish territories of Fernando Po and Río Muni (Spanish Guinea) became the independent state of the Republic of Equatorial Guinea in 1968. Patents are governed by Decree-Law 7/1987 of 1987, Decree No. 56 of 1990 and No. 38 of 1991.

Eritrea

The former Italian colony of Eritrea became federated with Ethiopia in 1852 and from 1962 until 1993 was fully integrated into Ethiopia as one of its 14 provinces. Eritrea became an independent country in 1993 and currently has no patent law. Since that time, it is no longer possible to seek patent protection in Eritrea through Ethiopia.

Ethiopia

Patents in Ethiopia are governed by Proclamation No. 123 of 1995.

Liberia

Patents in Liberia are governed by the Act Adopting a New Patent, Copyright and Trademark Law, Title 24, of 1972. Patents are granted for all inventions for a term of 20 years from the application filing date.

Foreigners who do not put a patented invention into active operation within three years from the grant date are deemed to have abandoned the patent to the public. The law also has a government use provision that only applies to patents that can be used in radio, television, telegraph, telephone or power stations.

Namibia

Namibia gained full independence in 1990, following its administration by South Africa since 1915 and as a German protectorate between 1884 and 1915. Patents are governed by Act No. 9 of 1916, Proclamation No. 17 of 1923 and Patent Rules of 1917, last amended in 1942, and South West African Affairs Act No. 25 of 1969. Patents are available for all inventions for a term of 14 years from the application filing date. Extension of the patent term is available from the Court on grounds of inadequate remuneration for seven, or in exceptional circumstances, for 14 years.

Patents must be exploited in such a manner that the reasonable requirements of the public are met within two years from grant, or they become subject to compulsory license. If the Court determines that the reasonable requirements of the public have not been met by the grant of a compulsory license, the patent may be revoked on the grounds of inadequate working after three years from patent grant.

Nigeria

Patents in Nigeria are governed by Patents and Designs Decree No. 60 of 1970, Patents and Designs Order of 1971, and Patents and Designs (Additional Transitional and Saving Provisions) Order of 1972.

Patents are granted for a term of 20 years from the application filing date, except that the following inventions are not patentable: plant or animal varieties, or essentially biological processes for the production of plants or animals (other than microbiological processes and their products); inventions the publication or exploitation of which would be contrary to public order or morality; and principles and discoveries of a mere scientific nature.

Compulsory licenses may be granted if, after four years from the filing or three years from patent grant, whichever is later, the invention has not been worked on a commercial scale so as to reasonably meet the demand in Nigeria; or the working is being prevented or hindered by the importation of the patented article; or that, by the failure of the patentee to grant licenses on reasonable terms, the establishment or

development of industrial or commercial activities in Nigeria is unfairly and substantially prejudiced. Dependent patent compulsory licenses are also available. Finally, the Commissioner of Patents may order that compulsory licenses and/or permission for importation may be granted for inventions of vital importance for the defense or economy of Nigeria or for public health.

Rwanda

Formerly Ruanda, part of the Belgian Trust-Territory of Ruanda-Urundi, Rwanda became independent in 1962. Patents are governed by the Patents Act of 1963 and Patents Regulations of 1967.

Patents are granted for all inventions for a term of 20 years from the application filing date. Although there are no provisions for compulsory licensing, any interested party may bring court action for the cancellation of a patent if the invention is not exploited in Rwanda within two years from the date of first commercial working abroad.

South Africa

The Patents Act (No. 57 of 1978), as last amended by Intellectual Property Laws Amendment Acts prior to 1998, and the Intellectual Property Laws Rationalisation Act of 1996, govern patents in South Africa. The Medicines and Related Substances Control Act of 1997 is discussed in Section 1.3 above.

Patents are granted for inventions for a term of 20 years from the application filing date but the following are not patentable: inventions the publication or exploitation of which would be generally expected to encourage offensive or immoral behavior; plant or animal varieties and essentially biological processes for the production of plants or animals, with the exception of microbiological processes thereof; methods of treatment of the human or animal body by surgery or therapy or of diagnosis practiced on the human or animal body. The law permits patenting of pharmaceutical substances.

The law permits government use and compulsory licensing under sections 4 and 56. Section 4 permits any Minister of State to use an invention for public purposes, either under agreement with the patent owner, or in the absence of agreement, under conditions as determined by the Commissioner of Patents after hearing from the patent owner. Section 56 provides for compulsory licensing for abuse of patent rights and for dependent patents. "Abuse of patents" is deemed to occur where the patented invention is not being worked in South Africa after the expiration of three years from grant or four years from filing, whichever is later, without satisfactory reason for non-working; where demand for the patented article in South Africa is not being met to an adequate extent and on reasonable terms; where because of the patent owner's refusal to grant a license on reasonable terms, the trade, industry or

agriculture of South Africa is being prejudiced; or where the patent owner, his/her licensee or agent is charging excessively high prices in relation to prices charged in other countries.

3.4 Results of Patent Surveys

The IIPI has conducted an analysis of what patents have been applied for in sub-Saharan African countries in respect of HIV/AIDS pharmaceuticals. In this regard we have written to the patent offices of all sub-Saharan African countries requesting them to provide information as to whether patents have been applied for, whether they have been granted and if granted, whether they are they still in force. This information was sought for the following pharmaceuticals (with the manufacturer noted):

Antiretrovirals – Nucleoside Analogs

Didanosine (Videx, ddI)	*Bristol Myers-Squibb*
Lamivudine (Epivir, 3TC)	*Glaxo Wellcome*[77]
Stavudine (Zerit, d4T)	*Bristol Meyers-Squibb*
Zalcitabine (Hivid, ddC)	*Hoffman-La Roche*
Zidovudine (Retrovir, AZT)	*Glaxo Wellcome*[78]
Abacavir (Ziagen)	*Glaxo Wellcome*

Antiretrovirals – Non Nucleosides

Delavirdine (Rescriptor)	*Upjohn*
Nevirapine (Viramune)	*Boehringer Ingelheim*
Efavirenz (Sustiva)	*DuPont Pharmaceuticals*

Antiretrovirals – Protease Inhibitors

Indinivir (Crixivan)	*Merck & Co*
Nelfinavir (Viracept)	*Agouron Pharmaceuticals*
Ritonavir (Norvir)	*Abbott*
Saquinavir (Invirase)	*Hoffman-La Roche*
Saquinavir (Fortovase)	*Hoffman-La Roche*
Amprenavir (Agenerase)	*Glaxo Wellcome*

In addition to requesting this information from the respective countries' patent offices, we have requested the information from ARIPO and OAPI and from the pharmaceutical companies manufacturing the drugs.

The information obtained from the patent offices and pharmaceutical companies is set out in the tables below. Where a patent is in force for a particular drug in a

[77] As will be evident from the tables below, the South African Medicines Control Council (MCC) approved and registered Combivir, a mix of Zidovudine (AZT) and Lamivudine (3TC) on 10 November 2000. The drug, however, will still not be available to the public sector, other than to health workers who are at risk through their occupation.

[78] See above note.

particular country, that box in the table is marked “yes”. Note that the responses to IIPI’s surveys, however, were incomplete. Hence this information should be considered indicative only. Of all the sub-Saharan African countries written to, only Malawi, Mauritius, The Democratic Republic of the Congo, Niger, Eritrea and Ethiopia responded. ARIPO replied on behalf of all its member countries. Of the drug companies written to, the following replied: Boehringer Ingelheim, Merck & Co, Abbott, Upjohn and Agouran (Pharmacia).

The IIPI has, in its recommendations, proposed the undertaking of a definite status report for not only antiretroviral drugs, but for all HIV/AIDS medications.

Patent Status of Nucleoside Analog ARV Drugs in sub-Saharan Africa

Country	AZT	DdI	ddC	d4T	3TC	Ziagen
Angola						
Benin						
Botswana						
Burkina Faso						
Burundi						
Cameroon						
Central African Rep.						
Chad						
Congo						
Ivory Coast						
Dem. Rep. Of Congo						
Djibouti						
Equitorial Guinea						
Eritrea						
Ethiopia						
Gabon						
Gambia						
Ghana						
Guinea						
Guinea-Bissau						
Kenya	**yes**				**yes**	
Lesotho						
Liberia						
Malawi						
Mali						
Mauritania						
Mauritius						
Mozambique						
Namibia						
Niger						
Nigeria						
Rwanda						
Senegal						
Sierra Leone						
Somalia						
South Africa	**yes***				**yes***	
Swaziland						
Togo						
Uganda						
Tanzania						
Zambia						
Zimbabwe						

***Approved by the MCC of South Africa as Combivir – a mix of Zidovudine (AZT and Lamivudine (3TC) on 11/10/00.**

Patent Status of Non-Nucleoside ARV Drugs in sub-Saharan Africa

Country	Rescriptor	Sustiva	Viramune
Angola			
Benin			
Botswana			**yes**
Burkina Faso			**yes**
Burundi			
Cameroon			
Central African Rep.			
Chad			
Congo			
Ivory Coast			
Dem. Rep. Of Congo			
Djibouti			
Equitorial Guinea			
Eritrea			
Ethiopia			**yes**
Gabon			
Gambia			**yes**
Ghana			
Guinea			
Guinea-Bissau			
Kenya			**yes**
Lesotho			**yes**
Liberia			
Malawi			**yes**
Mali			
Mauritania			
Mauritius			
Mozambique			
Namibia			
Niger			
Nigeria			
Rwanda			
Senegal			
Sierra Leone			
Somalia			
South Africa	**yes**	**yes**	**yes**
Swaziland			**yes**
Togo			
Uganda			**yes**
Tanzania			
Zambia			**yes**
Zimbabwe			**yes**

Patent Status of Protease Inhibitors in sub-Saharan Africa

Country	Crixivan	Viracept	Norvir	Invirase	Fortovase	Agenerase
Angola						
Benin						
Botswana						
Burkina Faso						
Burundi						
Cameroon						
Central African Rep.						
Chad						
Congo						
Ivory Coast						
Dem. Rep. of Congo	**yes**					
Djibouti						
Equitorial Guinea						
Eritrea						
Ethiopia						
Gabon						
Gambia						
Ghana						
Guinea						
Guinea-Bissau						
Kenya						
Lesotho						
Liberia						
Malawi						
Mali						
Mauritania						
Mauritius						
Mozambique						
Namibia						
Niger						
Nigeria						
Rwanda						
Senegal						
Sierra Leone						
Somalia						
South Africa	**yes**					
Swaziland						
Togo						
Uganda						
Tanzania						
Zambia						
Zimbabwe						

4. Conclusions

4.1 The TRIPS Agreement is Not the Problem

The TRIPS Agreement is not impeding access to medicines in sub-Saharan Africa. As outlined in Chapter 2 of this report, the TRIPS Agreement permits sufficient flexibility for African countries to expand access to HIV/AIDS drugs where other critical elements are in place, such as health care infrastructure and financing. Furthermore, for most sub-Saharan African countries, i.e., those that are designated as "least developed" by the United Nations, TRIPS obligations are not mandatory until 2006 at the earliest. The least developed countries in Sub-Saharan Africa include:

- 8 of the 15 members of OAPI, namely Benin, Burkina Faso, Central African Republic, Guinea, Mauritania, Niger, Chad and Togo;

- 7 of the 15 members of ARIPO, namely The Gambia, Lesotho, Malawi, Sierra Leone, Uganda, Tanzania, and Zambia; and

- 9 of the 12 other countries of continental sub-Saharan Africa, namely Angola, Burundi, Democratic Republic of Congo, Djibouti, Equatorial Guinea, Eritrea, Ethiopia, Liberia, and Rwanda.

Of the 16 sub-Saharan African countries in which more than one-tenth of the adult population is infected with HIV, 8 are least developed countries with no obligations under the TRIPS Agreement until at least 2006, namely Burundi, Central African Republic, Djibouti, Ethiopia, Lesotho, Malawi, Rwanda and Zambia.

The lack of access to medicines in sub-Saharan Africa is the result of a wide and complex range of causes. Laying blame for the problem on the WTO and the TRIPS Agreement is overly simplistic and wrong, and does nothing to alleviate the crisis.

4.2 Patents are Not the Problem

The patent issue, likewise, is dramatically overplayed in the discussions on access to HIV/AIDS medicines. The perception that patents are blocking access to HIV/AIDS drugs is also overly simplistic and incorrect.

As discussed in Chapter 3 of this report, our patent surveys shows that most antiretroviral medications are not widely patented in Africa. In the majority of countries of sub-Saharan Africa where no patents exist, there is still a dramatic lack of access to drugs. Similarly, there are tremendous access problems with medicines long ago off patent.

Where patents do exist, the TRIPS Agreement permits a great deal of flexibility to seek compulsory licenses or parallel imports of drugs under patent. The United States and European Union have indicated that they will not oppose such practices consistent with the TRIPS Agreement.

While it may be easy to use the drug industry as a scapegoat, patents are not blocking access to HIV/AIDS medications in sub-Saharan Africa. Even if antiretroviral HIV/AIDS drugs were made available free tomorrow, there is a lack of health care infrastructure to conduct testing, store and distribute medications, and monitor patient compliance with what are often very complicated regimens. Nils Daulaire, President of the Global Health Council, is among a growing chorus acknowledging that the challenge is much deeper than cheaper medications. "Even if AIDS drugs were free, no more than 10 to 20 percent of Africans would benefit as the health infrastructures do not exist to manage infections in each individual", he said.[79] Compounding the problem is the fact that in some countries, governments lack the political will to direct needed attention and resources to the problem of HIV/AIDS.

4.3 Financing is the Problem

It is increasingly widely accepted that the lack of availability of HIV/AIDS medicines is the result of a wide and complex range of causes, primary amongst which is a lack of financial resources to fund the health care system in general. Per capita incomes, and hence the availability of private resources for expenditures on medicines (whether generic or branded), are among the lowest in the world in sub-Saharan Africa. Governments also lack the resources to adequately fund health care infrastructure given their high debt burdens and the vast number of competing spending needs.

According to the WHO, public spending on drugs in over three dozen countries, many in sub-Saharan Africa, is less than $2 per capita per year. "In such countries, inadequate and misdirected financing is arguably the greatest barrier to access to life-saving essential drugs."[80] Further complicating the problem is the lack of insurance. Only 10.3% of the population of sub-Saharan Africa are covered by health insurance, requiring out-of-pocket expenditure that accounts for up to 80% of total health expenditures in some countries.[81] According to the WHO,

> *"Affordability of drugs could be increased substantially however, by eliminating or reducing import duties, distribution costs and dispensing fees. These can account for up to 80% of the total price paid for drugs. In particular, import duty can be as high as 30%,*

[79] Gumisai Mutume, "Development: Africa Shuns US Move Allowing Access to Cheaper AIDS Drugs", Inter Press Service, www.oneworld.org/ips2/July00/20_17_075.html, July 26
[80] *WHO Medicines Strategy 2000-2003* at p. 39.
[81] Ibid.

while value-added and other national and local taxes can amount to 20% of a drug cost.[82]

Current levels of foreign assistance are completely inadequate to support the needed costs to build the needed infrastructure and support drug purchase costs. This is true whether the purchase of generic drugs or patented drugs is involved. As noted recently in the newsletter of the AIDS advocacy organization Project Inform:

> *"The cost of drugs is only a small part of the problem. Building the necessary medical infrastructure will also be costly, as will be meeting the most fundamental needs for food and clean water. … President Clinton has declared the spread of AIDS in developing nations an urgent matter of US national security. If we believe this, then he and other western heads of state must begin to treat it as such. Just as they met to discuss intervention in Bosnia or to launch warfare against Iraq, they must now meet to plot out national and international strategy against this threat. They must begin negotiations and planning efforts with the heads of the affected nations, as well as grass roots representatives of the people in those nations. And they must begin to adjust their thinking in terms of dollars. Current efforts amount to a few hundred million dollars here and there, this from a country that spends roughly one and a half billion each time the space shuttle makes a supply run into orbit."*[83]

Renewed dedication from all quarters is urgently needed to stem the tide of suffering and death, to address the threat to peace and security and to make significant inroads in combating the HIV/AIDS epidemic in sub-Saharan. Significantly increased donor assistance is needed to build the needed health care infrastructure and to support drug purchases, whether generic or branded drugs is contemplated. Blaming the WTO, the TRIPS Agreement or patent holders for the lack of access to medicines will not further this effort.

It is evident from the research and the analysis presented above that the intellectual property rights of pharmaceutical companies and the TRIPS Agreement are not, in themselves, impediments to the availability of HIV/AIDS therapies in sub-Saharan Africa; and it is clearly incorrect to assume that without restrictions imposed by the WTO through TRIPS and without patents, HIV/AIDS patients would have access to drugs crucial to their survival. With such an enormous and impacting crisis as this, attention should properly be directed to the real factors constraining the availability of and access to these drugs in these countries.

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[82] Id. At p. 41.

[83] "Drug Pricing, AIDS and the Developing Nations", Project Inform *Perspective*, Number 30, August 2000, p. 14.

5. Recommendations

5.1 Changing Perceptions

5.1.1 WIPO should undertake a project to determine, definitively, the patent status of all HIV/AIDS medications in sub-Saharan Africa

Despite evidence that the TRIPS Agreement and patent protections generally do not block access to medicines in sub-Saharan Africa, there is, nevertheless a widespread perception that this is the case. Activists and the pharmaceutical industry have engaged in strong rhetoric that has failed in many cases to enlighten the debate on access to medicines and, rather, has led to distrust, accusation and counter-accusation.

It is the IIPI's view that WIPO is in a unique position to help elucidate the actual situation with regard to the role that the TRIPS Agreement and patents play with regard to access to HIV/AIDS drugs. WIPO may be in the best position to definitively determine, for example, the patent status of all of the HIV/AIDS drugs in the countries of sub-Saharan Africa. While the IIPI has made earnest attempts to determine patent status, it has only done so with regard to anti-retroviral drugs, and then with the caveats presented in this report.

WIPO has developed excellent working relationships with patent offices around the globe, it has highly skilled staff to undertake the analysis, and it has the international credibility to definitively speak to this subject. Despite all of the complexities involved, such as the shortcomings in electronic databases and inadequate staff in some patent offices, WIPO should be able to accomplish this project successfully. As noted in a later recommendation, "Enhanced WIPO Collaboration", this undertaking could prove to be very useful to international efforts to competitively procure HIV/AIDS medications in sub-Saharan Africa.

5.1.2 Interpreting TRIPS

With regard to the role that the TRIPS Agreement itself plays in this area, WIPO is in a more difficult position to address this problem. First, WIPO is constrained somewhat by the fact that it does not have the "authority" to interpret the TRIPS Agreement, since only the WTO has the final word on what particular provisions mean. Furthermore, in giving legal advice to countries, WIPO rightfully maintains confidentiality, akin to a lawyer-client relationship.

WIPO, nonetheless, can play an important role in helping to change perceptions regarding the role of the TRIPS Agreement with regard to access to medicines. First, although interpretation of the TRIPS Agreement is not clear in every respect, in most areas the agreement is quite clear, such as the transition periods, the meaning of most of the compulsory licensing provisions and the permissible exceptions to patent rights (e.g., permitting the so-called "Bolar" exemption). Second, the "TRIPS-plus"

policies of some governments have given way to recognition of permissible flexibility to address health crises. WIPO should not shy away from making this flexibility clear where appropriate.

5.2 TRIPS Implementation – Model Legislation and Training

In advising African countries on TRIPS and their patent legislation, WIPO should point out the flexibility provided by the TRIPS agreement outlined in Chapter 3 of this report. While "Bolar"-type exceptions to patent rights, compulsory licensing and parallel importation are perfectly legitimate under international rules, they may not achieve the desired effect absent adequate financing of health care infrastructure generally, and the specific prerequisites outlined by the WHO and dealt with above, being put into place.

The IIPI continues to believe that a model based on tiered pricing and prohibition of parallel imports would better serve the most needy countries. Structured programs, such as the pilot UNAIDS Drug Access Initiative, provide strong inducements for not only drug price reductions, but also for necessary investment in health care infrastructure to avoid diversion of drugs to the black market and the introduction of counterfeit and substandard drugs. This model also contemplates training of health care staff and patients to lessen the possibility that a drug resistant HIV strain will emerge.

The European Commission notes that "[e]xperience with vaccines and contraceptives demonstrates that significant price differentials can be achieved between prices in developed and developing countries", and endorses this approach, while warning that "[s]uch initiatives should be carefully monitored to ensure that scarce public finances that target prevention and services for the poorest and the many are not diverted to non-curative treatment for the few."[84]

The Pharmaceutical Research and Manufacturers of America explains its rationale for differential pricing:

> *"Having differential prices for pharmaceutical products makes them available to more consumers, at lower prices, than would be possible if only one price were permitted. When there are different prices across markets (e.g., lower prices in developing countries), manufacturers can maximize overall output and serve all markets. This benefits both developing countries (by increasing availability of products) and developed ones (by lowering prices through economies of scale)."*[85]

[84] Ibid at p. 12.

[85] Pharmaceutical Research and Manufacturers of America, Frequently Asked Questions, "Why do different people pay different prices for the same pharmaceutical product?" (at http://world.phrma.org/faq.html

5.3 Enhanced WIPO Collaboration

WIPO should actively engage in the international debates on access to HIV/AIDS medicines with other intergovernmental and non-governmental organizations. WIPO is recognized for its expertise in intellectual property matters, and has excellent relationships with its member states and industry.

In compiling a definitive list of the patent status of HIV/AIDS drugs, WIPO would be in the best position to assist procurement efforts of governments, international organizations and other purchasers.

WIPO should also contemplate the establishment of a joint WIPO-WHO consultative mechanism to ensure that both health and intellectual property experts are involved in the debates concerning access to drugs.

6. Country Profiles

ANGOLA

BASIC INDICATORS

POPULATION:	10,145,267
HIV INFECTION RATE:	2.78%
PER CAPITA GDP:	$1,030
LITERACY RATE:	42%
LIFE EXPECTANCY:	38.31 Years
INFANT MORTALITY RATE:	195.78 per 1000
DEBT (EXTERNAL):	$10.5 Billion

MEMBERSHIP IN SELECT IP TREATIES

WIPO CONVENTION:	1995
PARIS CONVENTION:	not a signatory
BERNE CONVENTION:	not a signatory
PATENT COOPERATION TREATY:	not a signatory
WTO TRIPS AGREEMENT:	1996
ARIPO OR OAPI:	not a signatory

PATENT STATISTICS (1998)

APPLICATIONS BY RESIDENTS:	n.a.
APPLICATIONS BY NON-RESIDENTS:	n.a.
TOTAL APPLICATIONS:	n.a.
PATENTS GRANTED TO RESIDENTS:	n.a.
PATENTS GRANTED TO NON-RESIDENTS:	n.a.
TOTAL PATENT GRANTS:	n.a.

BENIN

BASIC INDICATORS

POPULATION:	6,395,919
HIV INFECTION RATE:	2.45%
PER CAPITA GDP:	$1,300
LITERACY RATE:	37%
LIFE EXPECTANCY:	50.18 Years
INFANT MORTALITY RATE:	90.84 per 1000
DEBT (EXTERNAL):	$1.6 Billion

MEMBERSHIP IN SELECT IP TREATIES

WIPO CONVENTION:	1975
PARIS CONVENTION:	2000
BERNE CONVENTION:	1961
PATENT COOPERATION TREATY:	1987
WTO TRIPS AGREEMENT:	1996
ARIPO OR OAPI:	1977 OAPI

*PATENT STATISTICS (1998) (OAPI)**

APPLICATIONS BY RESIDENTS:	25
APPLICATIONS BY NON-RESIDENTS:	34,970
TOTAL APPLICATIONS:	34,995
PATENTS GRANTED TO RESIDENTS:	21
PATENTS GRANTED TO NON-RESIDENTS:	244
TOTAL PATENT GRANTS:	265

*These are the total statistics for all OAPI countries, used in absence of individual country statistics.

BOTSWANA

BASIC INDICATORS

POPULATION:	1,576,470
HIV INFECTION RATE:	35.80%
PER CAPITA GDP:	$3,900
LITERACY RATE:	37%
LIFE EXPECTANCY:	39.27 Years
INFANT MORTALITY RATE:	61.68 per 1000
DEBT (EXTERNAL):	$651 Million

MEMBERSHIP IN SELECT IP TREATIES

WIPO CONVENTION:	not a signatory
PARIS CONVENTION:	1998
BERNE CONVENTION:	1998
PATENT COOPERATION TREATY:	not a signatory
WTO TRIPS AGREEMENT:	1995
ARIPO OR OAPI:	1985 ARIPO

PATENT STATISTICS (1998)

APPLICATIONS BY RESIDENTS:	7
APPLICATIONS BY NON-RESIDENTS:	85
TOTAL APPLICATIONS:	92
PATENTS GRANTED TO RESIDENTS:	1
PATENTS GRANTED TO NON-RESIDENTS:	20
TOTAL PATENT GRANTS:	21

BURKINA FASO

BASIC INDICATORS

POPULATION:	11,946,065
HIV INFECTION RATE:	6.44%
PER CAPITA GDP:	$1,100
LITERACY RATE:	19.2%
LIFE EXPECTANCY:	46.73 Years
INFANT MORTALITY RATE:	108.53 per 1000
DEBT (EXTERNAL):	$1.3 Billion

MEMBERSHIP IN SELECT IP TREATIES

WIPO CONVENTION:	1975
PARIS CONVENTION:	1963
BERNE CONVENTION:	1963
PATENT COOPERATION TREATY:	1989
WTO TRIPS AGREEMENT:	1995
ARIPO OR OAPI:	1989 OAPI

*PATENT STATISTICS (1998) (OAPI)**

APPLICATIONS BY RESIDENTS:	25
APPLICATIONS BY NON-RESIDENTS:	34,970
TOTAL APPLICATIONS:	34,995
PATENTS GRANTED TO RESIDENTS:	21
PATENTS GRANTED TO NON-RESIDENTS:	244
TOTAL PATENT GRANTS:	265

*These are the total statistics for all OAPI countries, used in absence of individual country statistics.

BURUNDI

BASIC INDICATORS

POPULATION:	6,054,714
HIV INFECTION RATE:	11.32%
PER CAPITA GDP:	$730
LITERACY RATE:	35.30%
LIFE EXPECTANCY:	46.18 Years
INFANT MORTALITY RATE:	71.50 per 1000
DEBT (EXTERNAL):	$1.247 Billion

MEMBERSHIP IN SELECT IP TREATIES

WIPO CONVENTION:	not a signatory
PARIS CONVENTION:	1977
BERNE CONVENTION:	not a signatory
PATENT COOPERATION TREATY:	1977
WTO TRIPS AGREEMENT:	1995
ARIPO OR OAPI:	not a signatory

PATENT STATISTICS (1998)

APPLICATIONS BY RESIDENTS:	n.a.
APPLICATIONS BY NON-RESIDENTS:	n.a.
TOTAL APPLICATIONS:	n.a.
PATENTS GRANTED TO RESIDENTS:	n.a.
PATENTS GRANTED TO NON-RESIDENTS:	n.a.
TOTAL PATENT GRANTS:	n.a.

CAMEROON

BASIC INDICATORS

POPULATION:	15,421,937
HIV INFECTION RATE:	7.73%
PER CAPITA GDP:	$2,000
LITERACY RATE:	63.40%
LIFE EXPECTANCY:	54.82 Years
INFANT MORTALITY RATE:	70.87 per 1000
DEBT (EXTERNAL):	$11.5 Billion

MEMBERSHIP IN SELECT IP TREATIES

WIPO CONVENTION:	1973
PARIS CONVENTION:	1964
BERNE CONVENTION:	1977
PATENT COOPERATION TREATY:	1978
WTO TRIPS AGREEMENT:	1995
ARIPO OR OAPI:	1978 OAPI

*PATENT STATISTICS (1998) (OAPI)**

APPLICATIONS BY RESIDENTS:	25
APPLICATIONS BY NON-RESIDENTS:	34,970
TOTAL APPLICATIONS:	34,995
PATENTS GRANTED TO RESIDENTS:	21
PATENTS GRANTED TO NON-RESIDENTS:	244
TOTAL PATENT GRANTS:	265

*These are the total statistics for all OAPI countries, used in absence of individual country statistics.

CENTRAL AFRICAN REPUBLIC

BASIC INDICATORS

POPULATION:	3,512,751
HIV INFECTION RATE:	13.84%
PER CAPITA GDP:	$1,700
LITERACY RATE:	60%
LIFE EXPECTANCY:	44.02 Years
INFANT MORTALITY RATE:	106.69 per 1000
DEBT (EXTERNAL):	$790 Million

MEMBERSHIP IN SELECT IP TREATIES

WIPO CONVENTION:	1978
PARIS CONVENTION:	1963
BERNE CONVENTION:	1977
PATENT COOPERATION TREATY:	1978
WTO TRIPS AGREEMENT:	1995
ARIPO OR OAPI:	1978 OAPI

*PATENT STATISTICS (1998) (OAPI)**

APPLICATIONS BY RESIDENTS:	25
APPLICATIONS BY NON-RESIDENTS:	34,970
TOTAL APPLICATIONS:	34,995
PATENTS GRANTED TO RESIDENTS:	21
PATENTS GRANTED TO NON-RESIDENTS:	244
TOTAL PATENT GRANTS:	265

*These are the total statistics for all OAPI countries, used in absence of individual country statistics.

CHAD

BASIC INDICATORS

POPULATION:	8,424,504
HIV INFECTION RATE:	2.69%
PER CAPITA GDP:	$1,000
LITERACY RATE:	48.1%
LIFE EXPECTANCY:	50.49 Years
INFANT MORTALITY RATE:	96.66 per 1000
DEBT (EXTERNAL):	$1 Billion

MEMBERSHIP IN SELECT IP TREATIES

WIPO CONVENTION:	1970
PARIS CONVENTION:	1963
BERNE CONVENTION:	1971
PATENT COOPERATION TREATY:	1978
WTO TRIPS AGREEMENT:	1996
ARIPO OR OAPI:	1978 OAPI

*PATENT STATISTICS (1998) (OAPI)**

APPLICATIONS BY RESIDENTS:	25
APPLICATIONS BY NON-RESIDENTS:	34,970
TOTAL APPLICATIONS:	34,995
PATENTS GRANTED TO RESIDENTS:	21
PATENTS GRANTED TO NON-RESIDENTS:	244
TOTAL PATENT GRANTS:	265

*These are the total statistics for all OAPI countries, used in absence of individual country statistics.

THE REPUBLIC OF CONGO

BASIC INDICATORS

POPULATION:	2,830,961
HIV INFECTION RATE:	6.43%
PER CAPITA GDP:	$1,530
LITERACY RATE:	74.90%
LIFE EXPECTANCY:	47.43 Years
INFANT MORTALITY RATE:	101.55 per 1000
DEBT (EXTERNAL):	$5 Billion

MEMBERSHIP IN SELECT IP TREATIES

WIPO CONVENTION:	1975
PARIS CONVENTION:	1963
BERNE CONVENTION:	1962
PATENT COOPERATION TREATY:	1978
WTO TRIPS AGREEMENT:	1997
ARIPO OR OAPI:	1978 OAPI

*PATENT STATISTICS (1998) (OAPI)**

APPLICATIONS BY RESIDENTS:	25
APPLICATIONS BY NON-RESIDENTS:	34,970
TOTAL APPLICATIONS:	34,995
PATENTS GRANTED TO RESIDENTS:	21
PATENTS GRANTED TO NON-RESIDENTS:	244
TOTAL PATENT GRANTS:	265

*These are the total statistics for all OAPI countries, used in absence of individual country statistics.

IVORY COAST

BASIC INDICATORS

POPULATION:	15,980,950
HIV INFECTION RATE:	10.76%
PER CAPITA GDP:	$1,600
LITERACY RATE:	48.5%
LIFE EXPECTANCY:	45.15 Years
INFANT MORTALITY RATE:	95.06 per 1000
DEBT (EXTERNAL):	$16.8 Billion

MEMBERSHIP IN SELECT IP TREATIES

WIPO CONVENTION:	1974
PARIS CONVENTION:	1963
BERNE CONVENTION:	1962
PATENT COOPERATION TREATY:	1991
WTO TRIPS AGREEMENT:	1995
ARIPO OR OAPI:	1977 OAPI

*PATENT STATISTICS (1998) (OAPI)**

APPLICATIONS BY RESIDENTS:	25
APPLICATIONS BY NON-RESIDENTS:	34,970
TOTAL APPLICATIONS:	34,995
PATENTS GRANTED TO RESIDENTS:	21
PATENTS GRANTED TO NON-RESIDENTS:	244
TOTAL PATENT GRANTS:	265

*These are the total statistics for all OAPI countries, used in absence of individual country statistics.

DJIBOUTI

BASIC INDICATORS

POPULATION:	451,442
HIV INFECTION RATE:	11.75%
PER CAPITA GDP:	$1,200
LITERACY RATE:	46.2%
LIFE EXPECTANCY:	50.82 Years
INFANT MORTALITY RATE:	103.32 per 1000
DEBT (EXTERNAL):	$350 Million

MEMBERSHIP IN SELECT IP TREATIES

WIPO CONVENTION:	not a signatory
PARIS CONVENTION:	not a signatory
BERNE CONVENTION:	not a signatory
PATENT COOPERATION TREATY:	not a signatory
WTO TRIPS AGREEMENT:	1995
ARIPO OR OAPI:	not a signatory

PATENT STATISTICS (1998)

APPLICATIONS BY RESIDENTS:	n.a.
APPLICATIONS BY NON-RESIDENTS:	n.a.
TOTAL APPLICATIONS:	n.a.
PATENTS GRANTED TO RESIDENTS:	n.a.
PATENTS GRANTED TO NON-RESIDENTS:	n.a.
TOTAL PATENT GRANTS:	n.a.

DEMOCRATIC REPUBLIC OF CONGO

BASIC INDICATORS

POPULATION:	51,964,999
HIV INFECTION RATE:	5.07%
PER CAPITA GDP:	$710
LITERACY RATE:	77.3%
LIFE EXPECTANCY:	48.75 Years
INFANT MORTALITY RATE:	101.71 per 1000
DEBT (EXTERNAL):	$12.3 Billion

MEMBERSHIP IN SELECT IP TREATIES

WIPO CONVENTION:	1975
PARIS CONVENTION:	1975
BERNE CONVENTION:	1963
PATENT COOPERATION TREATY:	not a signatory
WTO TRIPS AGREEMENT:	1997
ARIPO OR OAPI:	not a signatory

PATENT STATISTICS (1998)

APPLICATIONS BY RESIDENTS:	n.a.
APPLICATIONS BY NON-RESIDENTS:	n.a.
TOTAL APPLICATIONS:	n.a.
PATENTS GRANTED TO RESIDENTS:	n.a.
PATENTS GRANTED TO NON-RESIDENTS:	n.a.
TOTAL PATENT GRANTS:	n.a.

EQUATORIAL GUINEA

BASIC INDICATORS

POPULATION:	474,214
HIV INFECTION RATE:	0.51%
PER CAPITA GDP:	$2,000
LITERACY RATE:	78.50%
LIFE EXPECTANCY:	53.56 Years
INFANT MORTALITY RATE:	94.83 per 1000
DEBT (EXTERNAL):	$290 Million

MEMBERSHIP IN SELECT IP TREATIES

WIPO CONVENTION:	1997
PARIS CONVENTION:	1997
BERNE CONVENTION:	1997
PATENT COOPERATION TREATY:	not a signatory
WTO TRIPS AGREEMENT:	not a signatory
ARIPO OR OAPI:	OAPI 1978

*PATENT STATISTICS (1988) (OAPI)**

APPLICATIONS BY RESIDENTS:	25
APPLICATIONS BY NON-RESIDENTS:	34,970
TOTAL APPLICATIONS:	34,995
PATENTS GRANTED TO RESIDENTS:	21
PATENTS GRANTED TO NON-RESIDENTS:	244
TOTAL PATENT GRANTS:	265

*These are the total statistics for all OAPI countries, used in absence of individual country statistics.

ERITREA

BASIC INDICATORS

POPULATION:	4,135,933
HIV INFECTION RATE:	2.87%
PER CAPITA GDP:	$750
LITERACY RATE:	25%
LIFE EXPECTANCY:	55.79 Years
INFANT MORTALITY RATE:	76.66 per 1000
DEBT (EXTERNAL):	$76 Million

MEMBERSHIP IN SELECT IP TREATIES

WIPO CONVENTION:	1997
PARIS CONVENTION:	not a signatory
BERNE CONVENTION:	not a signatory
PATENT COOPERATION TREATY:	not a signatory
WTO TRIPS AGREEMENT:	not a signatory
ARIPO OR OAPI:	not a signatory

PATENT STATISTICS (1998)

APPLICATIONS BY RESIDENTS:	n.a.
APPLICATIONS BY NON-RESIDENTS:	n.a.
TOTAL APPLICATIONS:	n.a.
PATENTS GRANTED TO RESIDENTS:	n.a.
PATENTS GRANTED TO NON-RESIDENTS:	n.a.
TOTAL PATENT GRANTS:	n.a.

ETHIOPIA

BASIC INDICATORS

POPULATION:	64,117,452
HIV INFECTION RATE:	10.63%
PER CAPITA GDP:	$560
LITERACY RATE:	35.50%
LIFE EXPECTANCY:	45.17 Years
INFANT MORTALITY RATE:	101.29 per 1000
DEBT (EXTERNAL):	$10 Billion

MEMBERSHIP IN SELECT IP TREATIES

WIPO CONVENTION:	1998
PARIS CONVENTION:	not a signatory
BERNE CONVENTION:	not a signatory
PATENT COOPERATION TREATY:	not a signatory
WTO TRIPS AGREEMENT:	not a signatory
ARIPO OR OAPI:	not a signatory

PATENT STATISTICS (1998)

APPLICATIONS BY RESIDENTS:	n.a.
APPLICATIONS BY NON-RESIDENTS:	n.a.
TOTAL APPLICATIONS:	n.a.
PATENTS GRANTED TO RESIDENTS:	n.a.
PATENTS GRANTED TO NON-RESIDENTS:	n.a.
TOTAL PATENT GRANTS:	n.a.

GABON

BASIC INDICATORS

POPULATION:	1,208,436
HIV INFECTION RATE:	4.16%
PER CAPITA GDP:	$6,500
LITERACY RATE:	63.2%
LIFE EXPECTANCY:	50.08 Years
INFANT MORTALITY RATE:	96.3 per 1000
DEBT (EXTERNAL):	$4.6 Billion

MEMBERSHIP IN SELECT IP TREATIES

WIPO CONVENTION:	1975
PARIS CONVENTION:	1964
BERNE CONVENTION:	1962
PATENT COOPERATION TREATY:	1978
WTO TRIPS AGREEMENT:	1995
ARIPO OR OAPI:	1978 OAPI

*PATENT STATISTICS (1998) (OAPI)**

APPLICATIONS BY RESIDENTS:	25
APPLICATIONS BY NON-RESIDENTS:	34,970
TOTAL APPLICATIONS:	34,995
PATENTS GRANTED TO RESIDENTS:	21
PATENTS GRANTED TO NON-RESIDENTS:	244
TOTAL PATENT GRANTS:	265

*These are the total statistics for all OAPI countries, used in absence of individual country statistics.

GAMBIA

BASIC INDICATORS

POPULATION:	1,367,124
HIV INFECTION RATE:	1.95%
PER CAPITA GDP:	$1,030
LITERACY RATE:	38,6%
LIFE EXPECTANCY:	53.20 Years
INFANT MORTALITY RATE:	79.29 per 1000
DEBT (EXTERNAL):	$430 Million

MEMBERSHIP IN SELECT IP TREATIES

WIPO CONVENTION:	1980
PARIS CONVENTION:	1992
BERNE CONVENTION:	1993
PATENT COOPERATION TREATY:	1997
WTO TRIPS AGREEMENT:	1996
ARIPO OR OAPI:	1978 ARIPO

PATENT STATISTICS (1998)

APPLICATIONS BY RESIDENTS:	5
APPLICATIONS BY NON-RESIDENTS:	60,267
TOTAL APPLICATIONS:	60,272
PATENTS GRANTED TO RESIDENTS:	1
PATENTS GRANTED TO NON-RESIDENTS:	17
TOTAL PATENT GRANTS:	18

GHANA

BASIC INDICATORS

POPULATION:	19,533,560
HIV INFECTION RATE:	3.60%
PER CAPITA GDP:	$1,900
LITERACY RATE:	64.50%
LIFE EXPECTANCY:	57.42 Years
INFANT MORTALITY RATE:	57.43 per 1000
DEBT (EXTERNAL):	$6 Billion

MEMBERSHIP IN SELECT IP TREATIES

WIPO CONVENTION:	1991
PARIS CONVENTION:	1976
BERNE CONVENTION:	1991
PATENT COOPERATION TREATY:	1997
WTO TRIPS AGREEMENT:	not a signatory
ARIPO OR OAPI:	1978 ARIPO

PATENT STATISTICS (1998)

APPLICATIONS BY RESIDENTS:	6
APPLICATIONS BY NON-RESIDENTS:	66,167
TOTAL APPLICATIONS:	66,173
PATENTS GRANTED TO RESIDENTS:	1
PATENTS GRANTED TO NON-RESIDENTS:	12
TOTAL PATENT GRANTS:	13

GUINEA

BASIC INDICATORS

POPULATION:	7,466,200
HIV INFECTION RATE:	1.54%
PER CAPITA GDP:	$1,200
LITERACY RATE:	35.90%
LIFE EXPECTANCY:	45.56 Years
INFANT MORTALITY RATE:	130.98 per 1000
DEBT (EXTERNAL):	$3.15 Billion

MEMBERSHIP IN SELECT IP TREATIES

WIPO CONVENTION:	1980
PARIS CONVENTION:	1982
BERNE CONVENTION:	1980
PATENT COOPERATION TREATY:	1991
WTO TRIPS AGREEMENT:	1995
ARIPO OR OAPI:	1991 OAPI

*PATENT STATISTICS (1998) (OAPI)**

APPLICATIONS BY RESIDENTS:	25
APPLICATIONS BY NON-RESIDENTS:	34,970
TOTAL APPLICATIONS:	34,995
PATENTS GRANTED TO RESIDENTS:	21
PATENTS GRANTED TO NON-RESIDENTS:	244
TOTAL PATENT GRANTS:	265

*These are the total statistics for all OAPI countries, used in absence of individual country statistics.

GUINEA-BISSAU

BASIC INDICATORS

POPULATION:	1,285,715
HIV INFECTION RATE:	2.50%
PER CAPITA GDP:	$900
LITERACY RATE:	53.9%
LIFE EXPECTANCY:	49.04 Years
INFANT MORTALITY RATE:	112.25 per 1000
DEBT (EXTERNAL):	$921 Million

MEMBERSHIP IN SELECT IP TREATIES

WIPO CONVENTION:	1988
PARIS CONVENTION:	1988
BERNE CONVENTION:	1991
PATENT COOPERATION TREATY:	1997
WTO TRIPS AGREEMENT:	1995
ARIPO OR OAPI:	1997 OAPI

PATENT STATISTICS (1998)

APPLICATIONS BY RESIDENTS:	n.a.
APPLICATIONS BY NON-RESIDENTS:	15,568
TOTAL APPLICATIONS:	15,568
PATENTS GRANTED TO RESIDENTS:	n.a.
PATENTS GRANTED TO NON-RESIDENTS:	n.a.
TOTAL PATENT GRANTS:	n.a.

KENYA

BASIC INDICATORS

POPULATION:	30,339,770
HIV INFECTION RATE:	13.95%
PER CAPITA GDP:	$1,600
LITERACY RATE:	78.1%
LIFE EXPECTANCY:	47.98 Years
INFANT MORTALITY RATE:	68.74 per 1000
DEBT (EXTERNAL):	$6.5 Billion

MEMBERSHIP IN SELECT IP TREATIES

WIPO CONVENTION:	1971
PARIS CONVENTION:	1965
BERNE CONVENTION:	1993
PATENT COOPERATION TREATY:	1994
WTO TRIPS AGREEMENT:	1995
ARIPO OR OAPI:	1978 ARIPO

PATENT STATISTICS (1998)

APPLICATIONS BY RESIDENTS:	33
APPLICATIONS BY NON-RESIDENTS:	67,797
TOTAL APPLICATIONS:	67,830
PATENTS GRANTED TO RESIDENTS:	8
PATENTS GRANTED TO NON-RESIDENTS:	93
TOTAL PATENT GRANTS:	101

LESOTHO

BASIC INDICATORS

POPULATION:	2,143,141
HIV INFECTION RATE:	23.57%
PER CAPITA GDP:	$2,240
LITERACY RATE:	71.3%
LIFE EXPECTANCY:	50.79 Years
INFANT MORTALITY RATE:	82.97 per 1000
DEBT (EXTERNAL):	$675 Million

MEMBERSHIP IN SELECT IP TREATIES

WIPO CONVENTION:	1986
PARIS CONVENTION:	1989
BERNE CONVENTION:	1989
PATENT COOPERATION TREATY:	1995
WTO TRIPS AGREEMENT:	1995
ARIPO OR OAPI:	1987 ARIPO

PATENT STATISTICS (1998)

APPLICATIONS BY RESIDENTS:	6
APPLICATIONS BY NON-RESIDENTS:	67,485
TOTAL APPLICATIONS:	67,491
PATENTS GRANTED TO RESIDENTS:	n.a.
PATENTS GRANTED TO NON-RESIDENTS:	36
TOTAL PATENT GRANTS:	36

LIBERIA

BASIC INDICATORS

POPULATION:	3,164,156
HIV INFECTION RATE:	2.80%
PER CAPITA GDP:	$1,000
LITERACY RATE:	38.3%
LIFE EXPECTANCY:	51.02 Years
INFANT MORTALITY RATE:	134.64 per 1000
DEBT (EXTERNAL):	$3 Billion

MEMBERSHIP IN SELECT IP TREATIES

WIPO CONVENTION:	1989
PARIS CONVENTION:	1994
BERNE CONVENTION:	1989
PATENT COOPERATION TREATY:	1994
WTO TRIPS AGREEMENT:	not a signatory
ARIPO OR OAPI:	not a signatory

PATENT STATISTICS (1998)

APPLICATIONS BY RESIDENTS:	n.a.
APPLICATIONS BY NON-RESIDENTS:	34,862
TOTAL APPLICATIONS:	34,862
PATENTS GRANTED TO RESIDENTS:	n.a.
PATENTS GRANTED TO NON-RESIDENTS:	n.a.
TOTAL PATENT GRANTS:	n.a.

MALAWI

BASIC INDICATORS

POPULATION:	10,385,849
HIV INFECTION RATE:	15.96%
PER CAPITA GDP:	$940
LITERACY RATE:	58%
LIFE EXPECTANCY:	37.58 Years
INFANT MORTALITY RATE:	122.28 per 1000
DEBT (EXTERNAL):	$2.3 Billion

MEMBERSHIP IN SELECT IP TREATIES

WIPO CONVENTION:	1970
PARIS CONVENTION:	1964
BERNE CONVENTION:	1991
PATENT COOPERATION TREATY:	1978
WTO TRIPS AGREEMENT:	1995
ARIPO OR OAPI:	1978 ARIPO

PATENT STATISTICS (1998)

APPLICATIONS BY RESIDENTS:	5
APPLICATIONS BY NON-RESIDENTS:	67,751
TOTAL APPLICATIONS:	67,756
PATENTS GRANTED TO RESIDENTS:	n.a.
PATENTS GRANTED TO NON-RESIDENTS:	76
TOTAL PATENT GRANTS:	76

MALI

BASIC INDICATORS

POPULATION:	10,685,948
HIV INFECTION RATE:	2.03%
PER CAPITA GDP:	$820
LITERACY RATE:	31%
LIFE EXPECTANCY:	46.66 Years
INFANT MORTALITY RATE:	123.25 per 1000
DEBT (EXTERNAL):	$3.1 Billion

MEMBERSHIP IN SELECT IP TREATIES

WIPO CONVENTION:	1982
PARIS CONVENTION:	1983
BERNE CONVENTION:	1962
PATENT COOPERATION TREATY:	1984
WTO TRIPS AGREEMENT:	1995
ARIPO OR OAPI:	1984 OAPI

*PATENT STATISTICS (1998) (OAPI)**

APPLICATIONS BY RESIDENTS:	25
APPLICATIONS BY NON-RESIDENTS:	34,970
TOTAL APPLICATIONS:	34,995
PATENTS GRANTED TO RESIDENTS:	21
PATENTS GRANTED TO NON-RESIDENTS:	244
TOTAL PATENT GRANTS:	265

*These are the total statistics for all OAPI countries, used in absence of individual country statistics.

MAURITANIA

BASIC INDICATORS

POPULATION:	2,667,859
HIV INFECTION RATE:	0.52%
PER CAPITA GDP:	$1,910
LITERACY RATE:	37.7%
LIFE EXPECTANCY:	50.76 Years
INFANT MORTALITY RATE:	78.15 per 1000
DEBT (EXTERNAL):	$2.5 Billion

MEMBERSHIP IN SELECT IP TREATIES

WIPO CONVENTION:	1976
PARIS CONVENTION:	1965
BERNE CONVENTION:	1973
PATENT COOPERATION TREATY:	1983
WTO TRIPS AGREEMENT:	1995
ARIPO OR OAPI:	1983 OAPI

*PATENT STATISTICS (1998) (OAPI)**

APPLICATIONS BY RESIDENTS:	25
APPLICATIONS BY NON-RESIDENTS:	34,970
TOTAL APPLICATIONS:	34,995
PATENTS GRANTED TO RESIDENTS:	21
PATENTS GRANTED TO NON-RESIDENTS:	244
TOTAL PATENT GRANTS:	265

*These are the total statistics for all OAPI countries, used in absence of individual country statistics.

MOZAMBIQUE

BASIC INDICATORS

POPULATION:	19,104,696
HIV INFECTION RATE:	13.22%
PER CAPITA GDP:	$1,000
LITERACY RATE:	40.1%
LIFE EXPECTANCY:	37.52 Years
INFANT MORTALITY RATE:	139.86 per 1000
DEBT (EXTERNAL):	$4,8 Billion

MEMBERSHIP IN SELECT IP TREATIES

WIPO CONVENTION:	1996
PARIS CONVENTION:	1998
BERNE CONVENTION:	not a signatory
PATENT COOPERATION TREATY:	2000
WTO TRIPS AGREEMENT:	1995
ARIPO OR OAPI:	2000 ARIPO

*PATENT STATISTICS (1998) (ARIPO)**

APPLICATIONS BY RESIDENTS:	24
APPLICATIONS BY NON-RESIDENTS:	34,591
TOTAL APPLICATIONS:	34,615
PATENTS GRANTED TO RESIDENTS:	1
PATENTS GRANTED TO NON-RESIDENTS:	88
TOTAL PATENT GRANTS:	89

*These are the total statistics for all ARIPO countries, used in absence of individual country statistics.

NAMIBIA

BASIC INDICATORS

POPULATION:	1,771,327
HIV INFECTION RATE:	19.54%
PER CAPITA GDP:	$4,300
LITERACY RATE:	38%
LIFE EXPECTANCY:	42.46 Years
INFANT MORTALITY RATE:	70.88 per 1000
DEBT (EXTERNAL):	159 Million

MEMBERSHIP IN SELECT IP TREATIES

WIPO CONVENTION:	1991
PARIS CONVENTION:	not a signatory
BERNE CONVENTION:	1990
PATENT COOPERATION TREATY:	not a signatory
WTO TRIPS AGREEMENT:	1995
ARIPO OR OAPI:	not a signatory

PATENT STATISTICS (1998)

APPLICATIONS BY RESIDENTS:	n.a.
APPLICATIONS BY NON-RESIDENTS:	n.a.
TOTAL APPLICATIONS:	n.a.
PATENTS GRANTED TO RESIDENTS:	n.a.
PATENTS GRANTED TO NON-RESIDENTS:	n.a.
TOTAL PATENT GRANTS:	n.a.

NIGER

BASIC INDICATORS

POPULATION:	10,075,511
HIV INFECTION RATE:	1.35%
PER CAPITA GDP:	$1.000
LITERACY RATE:	13.6%
LIFE EXPECTANCY:	41.27 Years
INFANT MORTALITY RATE:	124.9 per 1000
DEBT (EXTERNAL):	$1.3 Billion

MEMBERSHIP IN SELECT IP TREATIES

WIPO CONVENTION:	1975
PARIS CONVENTION:	1964
BERNE CONVENTION:	1962
PATENT COOPERATION TREATY:	1993
WTO TRIPS AGREEMENT:	1996
ARIPO OR OAPI:	1993 OAPI

*PATENT STATISTICS (1998) (OAPI)**

APPLICATIONS BY RESIDENTS:	25
APPLICATIONS BY NON-RESIDENTS:	34,970
TOTAL APPLICATIONS:	34,995
PATENTS GRANTED TO RESIDENTS:	21
PATENTS GRANTED TO NON-RESIDENTS:	244
TOTAL PATENT GRANTS:	265

*These are the total statistics for all OAPI countries, used in absence of individual country statistics.

NIGERIA

BASIC INDICATORS

POPULATION:	123,337,822
HIV INFECTION RATE:	5.06%
PER CAPITA GDP:	$970
LITERACY RATE:	57.1%
LIFE EXPECTANCY:	52.56 Years
INFANT MORTALITY RATE:	74.18 per 1000
DEBT (EXTERNAL):	$29 Billion

MEMBERSHIP IN SELECT IP TREATIES

WIPO CONVENTION:	1995
PARIS CONVENTION:	1963
BERNE CONVENTION:	1993
PATENT COOPERATION TREATY:	not a signatory
WTO TRIPS AGREEMENT:	1995
ARIPO OR OAPI:	not a signatory

PATENT STATISTICS (1998)

APPLICATIONS BY RESIDENTS:	n.a.
APPLICATIONS BY NON-RESIDENTS:	n.a.
TOTAL APPLICATIONS:	n.a.
PATENTS GRANTED TO RESIDENTS:	n.a.
PATENTS GRANTED TO NON-RESIDENTS:	n.a.
TOTAL PATENT GRANTS:	n.a.

RWANDA

BASIC INDICATORS

POPULATION:	7,229,129
HIV INFECTION RATE:	11.21%
PER CAPITA GDP:	$720
LITERACY RATE:	60.5%
LIFE EXPECTANCY:	39.34 Years
INFANT MORTALITY RATE:	120.06 per 1000
DEBT (EXTERNAL):	$1.2 Billion

MEMBERSHIP IN SELECT IP TREATIES

WIPO CONVENTION:	1984
PARIS CONVENTION:	1984
BERNE CONVENTION:	1984
PATENT COOPERATION TREATY:	not a signatory
WTO TRIPS AGREEMENT:	1996
ARIPO OR OAPI:	not a signatory

PATENT STATISTICS (1998)

APPLICATIONS BY RESIDENTS:	n.a.
APPLICATIONS BY NON-RESIDENTS:	n.a.
TOTAL APPLICATIONS:	n.a.
PATENTS GRANTED TO RESIDENTS:	n.a.
PATENTS GRANTED TO NON-RESIDENTS:	n.a.
TOTAL PATENT GRANTS:	n.a.

SENEGAL

BASIC INDICATORS

POPULATION:	9,987,494
HIV INFECTION RATE:	1.77%
PER CAPITA GDP:	$1,650
LITERACY RATE:	33.1%
LIFE EXPECTANCY:	62.19 Years
INFANT MORTALITY RATE:	58.05 per 1000
DEBT (EXTERNAL):	$3.4 Billion

MEMBERSHIP IN SELECT IP TREATIES

WIPO CONVENTION:	1970
PARIS CONVENTION:	1963
BERNE CONVENTION:	1962
PATENT COOPERATION TREATY:	1978
WTO TRIPS AGREEMENT:	1995
ARIPO OR OAPI:	1978 OAPI

*PATENT STATISTICS (1998) (OAPI)**

APPLICATIONS BY RESIDENTS:	25
APPLICATIONS BY NON-RESIDENTS:	34,970
TOTAL APPLICATIONS:	34,995
PATENTS GRANTED TO RESIDENTS:	21
PATENTS GRANTED TO NON-RESIDENTS:	244
TOTAL PATENT GRANTS:	265

*These are the total statistics for all OAPI countries, used in absence of individual country statistics.

SIERRA LEONE

BASIC INDICATORS

POPULATION:	5,232,624
HIV INFECTION RATE:	2.99%
PER CAPITA GDP:	$500
LITERACY RATE:	31.4%
LIFE EXPECTANCY:	45.25 Years
INFANT MORTALITY RATE:	148.66 per 1000
DEBT (EXTERNAL):	$1.15 Billion

MEMBERSHIP IN SELECT IP TREATIES

WIPO CONVENTION:	1986
PARIS CONVENTION:	1997
BERNE CONVENTION:	not a signatory
PATENT COOPERATION TREATY:	1997
WTO TRIPS AGREEMENT:	1995
ARIPO OR OAPI:	1980 ARIPO

PATENT STATISTICS (1998)

APPLICATIONS BY RESIDENTS:	n.a.
APPLICATIONS BY NON-RESIDENTS:	33,154
TOTAL APPLICATIONS:	33,154
PATENTS GRANTED TO RESIDENTS:	n.a.
PATENTS GRANTED TO NON-RESIDENTS:	n.a.
TOTAL PATENT GRANTS:	n.a.

SOMALIA

BASIC INDICATORS

POPULATION:	7,253,137
HIV INFECTION RATE:	2.99%
PER CAPITA GDP:	$600
LITERACY RATE:	24%
LIFE EXPECTANCY:	46.23 Years
INFANT MORTALITY RATE:	125.77 per 1000
DEBT (EXTERNAL):	$2.6 Billion

MEMBERSHIP IN SELECT IP TREATIES

WIPO CONVENTION:	1982
PARIS CONVENTION:	not a signatory
BERNE CONVENTION:	not a signatory
PATENT COOPERATION TREATY:	not a signatory
WTO TRIPS AGREEMENT:	not a signatory
ARIPO OR OAPI:	1981 ARIPO

*PATENT STATISTICS (1998) (ARIPO)**

APPLICATIONS BY RESIDENTS:	24
APPLICATIONS BY NON-RESIDENTS:	34,591
TOTAL APPLICATIONS:	34,615
PATENTS GRANTED TO RESIDENTS:	1
PATENTS GRANTED TO NON-RESIDENTS:	88
TOTAL PATENT GRANTS:	89

*These are the total statistics for all ARIPO countries, used in absence of individual country statistics.

SOUTH AFRICA

BASIC INDICATORS

POPULATION:	43,421,021
HIV INFECTION RATE:	19.94%
PER CAPITA GDP:	$6,900
LITERACY RATE:	81.8%
LIFE EXPECTANCY:	51.5 Years
INFANT MORTALITY RATE:	58.88 per 1000
DEBT (EXTERNAL):	$25.7 Billion

MEMBERSHIP IN SELECT IP TREATIES

WIPO CONVENTION:	1975
PARIS CONVENTION:	1947
BERNE CONVENTION:	1928
PATENT COOPERATION TREATY:	1999
WTO TRIPS AGREEMENT:	1995
ARIPO OR OAPI:	not a signatory

PATENT STATISTICS (1995)

APPLICATIONS BY RESIDENTS:	5,549
APPLICATIONS BY NON-RESIDENTS:	5,501
TOTAL APPLICATIONS:	11,050
PATENTS GRANTED TO RESIDENTS:	n.a.
PATENTS GRANTED TO NON-RESIDENTS:	n.a.
TOTAL PATENT GRANTS:	5,453

NOTE: 1995 is most current year for which WIPO statistics are available.

SWAZILAND

BASIC INDICATORS

POPULATION:	1,083,289
HIV INFECTION RATE:	25.25%
PER CAPITA GDP:	$4,200
LITERACY RATE:	76.7%
LIFE EXPECTANCY:	40.44 Years
INFANT MORTALITY RATE:	108.95 per 1000
DEBT (EXTERNAL):	$180 Million

MEMBERSHIP IN SELECT IP TREATIES

WIPO CONVENTION:	1988
PARIS CONVENTION:	1991
BERNE CONVENTION:	1998
PATENT COOPERATION TREATY:	1994
WTO TRIPS AGREEMENT:	1995
ARIPO OR OAPI:	1987 ARIPO

PATENT STATISTICS (1998)

APPLICATIONS BY RESIDENTS:	6
APPLICATIONS BY NON-RESIDENTS:	34,529
TOTAL APPLICATIONS:	34,535
PATENTS GRANTED TO RESIDENTS:	n.a.
PATENTS GRANTED TO NON-RESIDENTS:	63
TOTAL PATENT GRANTS:	63

UNITED REPUBLIC OF TANZANIA

BASIC INDICATORS

POPULATION:	35,306,126
HIV INFECTION RATE:	8.09%
PER CAPITA GDP:	$550
LITERACY RATE:	67.8%
LIFE EXPECTANCY:	52.26 Years
INFANT MORTALITY RATE:	80.97 per 1000
DEBT (EXTERNAL):	$7.7 Billion

MEMBERSHIP IN SELECT IP TREATIES

WIPO CONVENTION:	1983
PARIS CONVENTION:	1963
BERNE CONVENTION:	1994
PATENT COOPERATION TREATY:	1999
WTO TRIPS AGREEMENT:	1995
ARIPO OR OAPI:	1983 ARIPO

PATENT STATISTICS (1998)

APPLICATIONS BY RESIDENTS:	n.a.
APPLICATIONS BY NON-RESIDENTS:	n.a.
TOTAL APPLICATIONS:	n.a.
PATENTS GRANTED TO RESIDENTS:	n.a.
PATENTS GRANTED TO NON-RESIDENTS:	n.a.
TOTAL PATENT GRANTS:	10

TOGO

BASIC INDICATORS

POPULATION:	5,018,502
HIV INFECTION RATE:	5.98%
PER CAPITA GDP:	$1,700
LITERACY RATE:	51.7%
LIFE EXPECTANCY:	54.69 Years
INFANT MORTALITY RATE:	71.55 per 1000
DEBT (EXTERNAL):	$1.3 Billion

MEMBERSHIP IN SELECT IP TREATIES

WIPO CONVENTION:	1974
PARIS CONVENTION:	1967
BERNE CONVENTION:	1975
PATENT COOPERATION TREATY:	1978
WTO TRIPS AGREEMENT:	1995
ARIPO OR OAPI:	1978 OAPI

*PATENT STATISTICS (1998) (OAPI)**

APPLICATIONS BY RESIDENTS:	25
APPLICATIONS BY NON-RESIDENTS:	34,970
TOTAL APPLICATIONS:	34,995
PATENTS GRANTED TO RESIDENTS:	21
PATENTS GRANTED TO NON-RESIDENTS:	244
TOTAL PATENT GRANTS:	265

*These are the total statistics for all OAPI countries, used in absence of individual country statistics.

UGANDA

BASIC INDICATORS

POPULATION:	23,317,560
HIV INFECTION RATE:	8.30%
PER CAPITA GDP:	$1,060
LITERACY RATE:	61.8%
LIFE EXPECTANCY:	42.93 Years
INFANT MORTALITY RATE:	93.25 per 1000
DEBT (EXTERNAL):	$3.1 Billion

MEMBERSHIP IN SELECT IP TREATIES

WIPO CONVENTION:	1973
PARIS CONVENTION:	1965
BERNE CONVENTION:	not a signatory
PATENT COOPERATION TREATY:	1995
WTO TRIPS AGREEMENT:	1995
ARIPO OR OAPI:	1978 ARIPO

PATENT STATISTICS (1998)

APPLICATIONS BY RESIDENTS:	7
APPLICATIONS BY NON-RESIDENTS:	67,603
TOTAL APPLICATIONS:	67,610
PATENTS GRANTED TO RESIDENTS:	n.a.
PATENTS GRANTED TO NON-RESIDENTS:	66
TOTAL PATENT GRANTS:	66

ZAMBIA

BASIC INDICATORS

POPULATION:	9,582,418
HIV INFECTION RATE:	19.95%
PER CAPITA GDP:	$880
LITERACY RATE:	78.2%
LIFE EXPECTANCY:	37.24 Years
INFANT MORTALITY RATE:	92.38 per 1000
DEBT (EXTERNAL):	$6.7 Billion

MEMBERSHIP IN SELECT IP TREATIES

WIPO CONVENTION:	1977
PARIS CONVENTION:	1965
BERNE CONVENTION:	1992
PATENT COOPERATION TREATY:	not a signatory
WTO TRIPS AGREEMENT:	1995
ARIPO OR OAPI:	1978 ARIPO

PATENT STATISTICS (1998)

APPLICATIONS BY RESIDENTS:	7
APPLICATIONS BY NON-RESIDENTS:	86
TOTAL APPLICATIONS:	93
PATENTS GRANTED TO RESIDENTS:	1
PATENTS GRANTED TO NON-RESIDENTS:	19
TOTAL PATENT GRANTS:	20

ZIMBABWE

BASIC INDICATORS

POPULATION:	11,342,521
HIV INFECTION RATE:	25.06%
PER CAPITA GDP:	$2,400
LITERACY RATE:	85%
LIFE EXPECTANCY:	37.78 Years
INFANT MORTALITY RATE:	62.25 per 1000
DEBT (EXTERNAL):	$5 Billion

MEMBERSHIP IN SELECT IP TREATIES

WIPO CONVENTION:	1981
PARIS CONVENTION:	1980
BERNE CONVENTION:	1980
PATENT COOPERATION TREATY:	1997
WTO TRIPS AGREEMENT:	1995
ARIPO OR OAPI:	1980 ARIPO

PATENT STATISTICS (1998)

APPLICATIONS BY RESIDENTS:	8
APPLICATIONS BY NON-RESIDENTS:	66,264
TOTAL APPLICATIONS:	66,272
PATENTS GRANTED TO RESIDENTS:	1
PATENTS GRANTED TO NON-RESIDENTS:	29
TOTAL PATENT GRANTS:	30

Note: Basic Indicators are from the CIA World Fact Book 2000, with the exception of HIV Infection Rate, which is from UNAIDS "Report on the Global HIV/AIDS Epidemic", June 2000, at www.unaids.org/epidemic_update/report/Table_E.htm updated on 7/3/00. Information on treaty membership and patent statistics is from WIPO and WTO (www.wipo.org and www.wto.org).

7. Definitions and Terminology

"Bolar" Exception:	an exception to the patent rights that permits the use of a patented drug for testing purposes for submission of test data required by regulatory authorities.
Compulsory license:	a license granted by the government to itself or a third party to practice an invention without the permission of the patent owner, usually on grounds of public interest, national emergency, or anti-competitive behavior by the patent owner.
Generic drug:	a pharmaceutical product that is not protected by a patent, and which is usually introduced after the expiration of patent or other exclusive rights.
Parallel imports:	products imported from another country, without the permission of the patent owner, when those products have been sold in other markets by the patent owner or his/her licensee.
Patent:	a right granted by the government to an innovator to exclude others from practicing the invention for a limited time (20 years from filing the application) in exchange for full disclosure of the invention, which leads to future innovation.