

**AFRICAN AIDS: IMPACTS OF GLOBALIZATION, PHARMACEUTICAL  
APARTHEID, AND TREATMENT ACTIVISM**  
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BACKGROUND REALITIES OF THE AFRICAN AIDS PANDEMIC

There is no doubt that South Africa in particular and sub-Saharan Africa as a whole are in the middle of an HIV/AIDS crisis of catastrophic proportions – each day, each and every day, 6000 Africans die of AIDS, twice the number who died at the World Trade Center on September 11, 2001. Available data indicates that 4.7-5.4 million South Africans are currently infected as of December 2001, approximately 22% of the adult population ages 15-49.<sup>2</sup> Throughout sub-Saharan Africa, 28.1 million people are infected, 70% of the worldwide total of 40 million.<sup>3</sup> Because the pandemic has exploded within the past decade, the death toll is mounting – 250,000 AIDS funerals in South Africa last year, 2.3 million in southern Africa, 3 million worldwide, all adding to the 24.8 million cumulative deaths since the start of the pandemic, three quarters of which, 19.3 million, have been in Africa.<sup>4</sup>

Worldwide, but especially in Africa, a disproportionate number of infections occur in late teenage and young adult years.<sup>5</sup> Although HIV/AIDS in Africa affects both men and women, women now have a higher overall infection rate than men,<sup>6</sup> and women contract the virus at a much younger age, 5-10 years earlier,<sup>7</sup> because of numerous co-factors, including cross-age sex between younger teenage women and older, already infected men,<sup>8</sup> the effects of young age and STD's on vaginal susceptibility to viral transmission,<sup>9</sup> and lack of power of younger women to

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<sup>2</sup> UNAIDS, *Report on the Global Aids Epidemic* 124 (July 2000) estimated that approximately 4,200,000 persons in South Africa were living with HIV/AIDS at the end of 1999 (lowest estimate 3,400,000, highest 5,200,000). The December 2001 *UNAIDS AIDS Epidemic Update* put the total at 4.7 million. Two South African studies released in 2001 gave estimates of 4.7 million and 5.4 million. The June 2000 estimated population of South Africa was 43.4 million. Population Reference Bureau, *2000 World Population Data Sheet*.

<sup>3</sup> *UNAIDS AIDS Epidemic Update* (Dec. 2001).

<sup>4</sup> *Id.* There has been some controversy about the accuracy of UNAIDS estimates of HIV incidence and AIDS death statistics. Rian Malan, *AIDS in Africa: In Search of the Truth*, *Rolling Stone* 71 (Nov. 22, 2001). All estimates are based on incomplete sampling and projection models based on relatively small numbers; this doesn't mean that the numbers are made up.

<sup>5</sup> In South Africa, sixty percent of new infections are in the 15-25 age group. Abt Associates of South Africa, Inc., *The Impending Catastrophe: A Resource Book on the Emerging HIV/AIDS Epidemic in South Africa* (2000). Worldwide, over half the persons living with HIV/AIDS became infected with HIV between the ages of 15 and 24. An estimated 11.8 million young people are living with HIV. Karungari Kiagu, *Youth and HIV/AIDS: Can We Avoid Catastrophe?*, XXIX Population Reports, Series L, Number 12, 6 (Fall 2001).

<sup>6</sup> *UNAIDS Report*, *supra* note 2, at 124 (reporting that 2,300,000 out of 4,200,000 infections are in women). Among young people, the disparity is even more pronounced, 7.3 million of 11.8 million infected youths are female. Kiagu, *supra* note \*, at 6.

<sup>7</sup> Primary periods of infection are between ages 15-19 for women and ages 20-29 for men. S.A. Medical Research Council, *The Impact of HIV/AIDS on Adult Mortality in South Africa* (Sept. 2001).

<sup>8</sup> Sexual exploitation of young girls and coercive sexual initiation are widespread phenomena, particularly at schools by both teachers and peers. Human Rights Watch, *Scared At School: Sexual Violence Against Girls in South African Schools* (2001) <http://www.hrw.org/reports/2001/safrica/>.

<sup>9</sup> *Id.* at 46-49. Younger women are particularly vulnerable to reproductive tract infections that contribute to HIV vulnerability because adolescent women have fewer protective antibodies than do older women and

negotiate safer sex practices. Although South African statistics reveal a roughly 24.5% infection rate in women at antenatal clinics, the rate is much higher in some provinces, particularly KwaZulu Natal, ground zero of the pandemic, where more than 36% of pregnant women test HIV positive.<sup>10</sup> Likewise, the infection rate spikes much higher in certain mining communities, as high as 60% in some prenatal screening programs.<sup>11</sup> At present rates of infection, the typical South African 15 year old has more than a 50% probability of dying of AIDS; for teenagers living in KwaZulu Natal or in neighboring Botswana, the likelihood of dying of AIDS exceeds 85%.

A particularly devastating aspect of the disease is that it can be transmitted vertically from mother to child during pregnancy, delivery, and/or breast-feeding.<sup>12</sup> Thus, approximately, 70,000-100,000 cases of mother-to-child transmission occur each year in South Africa alone, another 600,000 in the rest of Africa. Although effective and low-cost anti-retroviral treatment protocols can reduce this transmission by as much as 50%, such treatment is not yet widely available.<sup>13</sup> Belatedly, the South African government is starting an HIV testing/counseling and inexpensive anti-retroviral program that will initially reach approximately 10% of South Africa's 1.2 million pregnant women. The failure of the ANC government to address mother-to-child-transmission (MTCT) earlier and more comprehensively has been one of its most grievous political errors and a particularly contentious issue in South Africa even among old allies.<sup>14</sup> In fact, the South African government has been sued for its failure to institute a comprehensive MTCT prevention program and to provide a two-dose nevirapine regime in the public sector. The government lost the suit on December 14, 2001, but has announced its intention to appeal the judgment to the Constitutional Court.

HIV/AIDS affects all racial groups in South Africa, but the infection rate for Black Africans (13%) is by far the highest because of co-factors associated with poverty, including reduced nutrition, reduced access to primary health care, increased exposure to opportunistic and debilitating diseases, and disrupted family structures leading to multi-partner sexual activity. The infection rate is high, but not as high in Coloured communities (3%) and lower yet in white and Indian communities (1-2%) where the general state of health, access to health care, and more stabilized family structures decreases exposure to HIV and increases resistance to the disease and its progress.<sup>15</sup>

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because the immaturity of their cervixes increases the likelihood that exposure to infection will result in the transmission of the disease. Recent studies have found that 52% of women seen in public health clinics in KwaZulu Natal province on any particular day are likely to be suffering from an untreated STD. Strum et al., *Pregnant Women as a Reservoir of Undetected Sexually Transmitted Disease in Rural South Africa: Implications for Disease Control*, 88(8) Am. J. Public Health 1243-45 (1998). This is an important factor in the escalating incident of HIV infection in sexually active women. In addition to STDs, other untreated reproductive tract infections can increase susceptibility to transmission.

<sup>10</sup> HIV InSite, *South Africa* <http://hivinsite.ucsf.edu/international/africa/2098.410f.html> (August 17, 2000).

<sup>11</sup> UNAIDS Report, *supra* note 2, at 11-12 (reporting infection rates in Carletonville South Africa among younger women.).

<sup>12</sup> Approximately one third of HIV-positive women will transmit HIV infection vertically to their children during pregnancy, childbirth, or breast-feeding. *Id.* at 81.

<sup>13</sup> *Id.* at 82 (reporting positive results from a single dose of Nevirapine during delivery to the mother and another shortly thereafter to the infant – total cost of medicine app. \$4.00). In the U.S., with active ARV treatment of the mother, caesarian deliveries, and substitution of formula for breast milk, MTCT rates are as low as 2%.

<sup>14</sup> Although many of the founding members of the access to treatment movement in South Africa were gay activists, current ANC and former ANC comrades from the health care and children's rights sectors have quickly joined their ranks. In late 2000, COSATU, the South African Communist Party, and the religious community joined the call for comprehensive prevention of mother-to-child-transmission.

<sup>15</sup> These estimates come from South Africa Business Daily, August \*, 2000. Note: the racial composition of South Africa is 75.2% Black, 13.6% White, 8.6% "Coloured," and 2.6% Indian. U.S. State Department statistics.

Currently, anti-retroviral drugs (ARVs) and drugs for opportunistic illnesses (OIs) are not readily available in Africa. Thus, as of December, 2001, only 30,000 Africans are receiving ARV therapy out of 28 million infected persons, 3-4 million of whom should be on ARVs. Even in South Africa, sub-Saharan Africa's richest economy, only 10,000 patients are receiving ARVs,<sup>16</sup> a tiny subset of the 19% of the population in the private health sector.<sup>17</sup> For the vast majority of South Africans, their only access to health care is through the public health sector which is poorly resourced, overtaxed, and disorganized. Persons living with HIV/AIDS using the public health sector do not have any legally authorized access to anti-retroviral medications nor to many of the treatments and medications used against killer opportunistic infections, with the very recent exception of free fluconazole. Accordingly, the vast majority of South Africans with HIV/AIDS, men, women, children, and babies, mostly Black,<sup>18</sup> are told not to come back for treatment once they are diagnosed with HIV. In effect, they are told to go home and die.

The consequences of the HIV/AIDS pandemic for the development and transformation of Africa are truly frightening. Economically, there will be dramatic losses of life resulting in much higher labor turnover rates, training costs, etc., all of which will negatively impact growth in domestic production and job creation.<sup>19</sup> Likewise, there will be much more absenteeism from work, both those who are sick and those taking care of the ill.<sup>20</sup> The incapacity of the workforce will be particularly devastating in the agricultural sector where fewer and less productive farm workers will exacerbate food insecurity leading to increased rates of starvation and malnutrition, which in turn leads to increased susceptibility to disease including HIV.<sup>21</sup> Finally, the internal market for goods will be negatively impacted as the number of consumers, and their buying power, is reduced and as a growing percentage of the gross domestic product is diverted to medical, care-taking, and funeral costs.

Socially, the impact is even more devastating. Certain communities will experience drastic losses of population, especially of young people in their most productive years, including teachers, medical workers, community activists, political and traditional leaders, etc.<sup>22</sup> Because of the death of young parents in the prime of their lives, there are currently hundreds of thousands

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<sup>16</sup> Business Daily \*

<sup>17</sup> Only 19% of South Africans were in the private health care system in 1999, approximately 77% of whites, 31% of Indians, 23% of Coloureds, and 11% of Black Africans. *Second Kaiser Family Foundation Report on Health Care in South Africa* (1999). Private coverage has since gone down to approximately 17%. Even in the private sector, access to medicines is limited because less than one third of South Africa's medical aid plans offer any HIV/AIDS treatment benefits, with annual benefits capped at \$2000-\$3300, far less than standard HIV treatment costs. Thus, even in the private sector, only a small number of infected South Africans, for example Constitutional Court Justice Edwin Cameron, can receive anti-retrovirals and other drugs at high cost either because their medical aid plans cover such costs or because they are wealthy enough to afford the medicines on their own.

<sup>18</sup> Approximately 98% of persons infected with HIV/AIDS in South Africa are Black Africans (not including Coloured and Indians).

<sup>19</sup> By a recent estimate, the South African economy will be 17%-20% smaller in 2010 than it would have been in the absence of the HIV/AIDS pandemic. Howard Barrell, *AIDS Wreaks Havoc on the Economy*, Daily Mail and Guardian (Oct. 3, 2000) <http://www.mg.co.za/za/features/2000oct/03-economy.html> (10/03/2000) (reporting on a paper entitled *The Macro Implications of HIV/Aids in South Africa: A Preliminary Assessment*).

<sup>20</sup> See also HIV InSite, *supra* note 6 at 7-10.

<sup>21</sup> Committee on World Food Security, *The Impact of HIV/AIDS on Food Security* (Food and Agriculture Organization of the United Nation – 27<sup>th</sup> Session, Rome May 28 – June 1, 2001). <http://www.fao.org/docrep/meetings/003/Y0310E.htm> (5/14/2001); Committee on World Food Security, *State of Food and Agriculture 2001* (Food and Agriculture Organization of the United Nation 2001). <http://www.fao.org/DOCREP/003/X9800E/x9800e08.htm> (9/14/01).

<sup>22</sup> *Id.* It is estimated that KwaZulu Natal will have to replace its entire core of teachers in the next ten years.

of AIDS orphans in South Africa,<sup>23</sup> 13 million in sub-Saharan Africa – children who are left on their own, without the benefit of parental supervision, support, and nurture, frequently without the benefit of further education, exposed to the uncertainty of living on their own or on the streets.<sup>24</sup> By 2010, it is estimated that there will be nearly 40 million orphans in Africa, over 30 million AIDS orphans, a number roughly equivalent to the number of school-age children in the U.S. who live east of the Mississippi.

#### CONTEXTUALIZING THE PANDEMIC – HOW POVERTY CONTRIBUTES TO HIV/AIDS

The impact of poverty in Africa, made worse by the cruel machinations of globalization, is certainly a factor in the African HIV/AIDS crisis. Although there is no credible doubt that HIV causes AIDS, there is considerable confusion about how poverty exacerbates or contributes to the HIV/AIDS pandemic.<sup>25</sup> Public awareness in the U.S. tends to focus on the racist specter of Africans having promiscuous, unsafe sex<sup>26</sup> and on Africans' alleged resistance to prevention campaigns and a culture of denial. Similarly, the political culture of prevention tends to focus on the ABC's of sexual behavior, "abstain, be faithful, condomize," thereby individualizing the pandemic. Thus, increased understanding about the structural impacts of poverty on the incidence of HIV/AIDS is important both to counteract the typical, and racist, blame-the-victim response and to assess the importance of local and global poverty alleviation strategies as additional tools in fighting the pandemic. Tracing the sources of African poverty, in both colonial and neo-colonial practices, is also crucial in catalyzing public opinion and policy responses to a crisis the U.S. government, international organizations, and the pharmaceutical industry have helped to create.

To understand the multiple and complex impacts of poverty, it is helpful to separate poor health and poor health care effects from a number of other poverty-related social and economic effects arising from histories of colonialism, racism, and patriarchy and from effects of poor information and poor education. Likewise, in the section that follows, it is useful to contextualize the stark reality of poverty/AIDS in Africa within the actions and inaction of the major powers, including the U.S., which have failed to address, and in fact have complicated, poverty and AIDS crises in Africa through callous trade and debt policies, policies made morally possible only when rich countries discount the dignity and worth of poor people, particularly black people.

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<sup>23</sup> Currently, the estimate is that there are 420,000 AIDS orphans in South Africa. UNAIDS Report, *supra* note 2, at 124.

<sup>24</sup> Children's Rights Center, *Children's Rights Manual* \* (2000); Susan Hunter & John Williamson, *Children on the Brink 2000* (USAID 2000); *Children Orphaned by AIDS: Front-Line Responses from Eastern and Southern Africa* (UNAIDS & UNICEF 2001).

<sup>25</sup> One difficulty of talking about how poverty "interacts with," is a "key determinant of," or even "causes" HIV/AIDS is how such formulations resonate with President Thabo Mbeki's torturous courtship of HIV dissidents and his corresponding attempt to label poverty as a "cause" (not just a co-factor) of HIV. For example, in a recent TIME Magazine interview, Mbeki has suggested that poverty and tuberculosis can be "causes" of AIDS even in the absence of HIV infection or even more erroneously that TB can cause one to test positive for HIV. Given Mbeki's "new science" and the confusion he has created on the ground in South Africa (and perhaps even in the U.S.), any discussion of the "connection" between AIDS and poverty must attempt to clarify the role of poverty in "exacerbating" the AIDS pandemic but not "causing" it in the absence of the HIV virus.

<sup>26</sup> Eileen Stillwaggon, *AIDS and Poverty in Africa*, *The Nation* 22, 23 (May 21, 2001); Eileen Stillwaggon, *Racial Meaphors: Interpreting Sex and AIDS in Africa* (draft 2000). The 2001 Durex Global Sex Survey carried out 28 countries worldwide found that South Africans have sex fewer times per year than Americans, that they keep their virginity until a later age (17.2 vs. 16) and that they have fewer sexual partners, averaging 8.2 versus 14.3 in the U.S. *South Africans Still Take Risks Despite AIDS Fears*. ZANOW Daily Mail & Guardian, November 27, 2001.

### *Poor Health and Poor Health Care Effects*

The chain of argument about the direct impacts of poverty- and inequality-related *poor-health* and *poor health care* on the incidence of HIV infection is as follows: (1) poverty<sup>27</sup> reduces resistance to infectious disease in general because of poor nutrition and harsh living conditions, including poor access to clean water and sanitation;<sup>28</sup> (2) because of poorly resourced and inaccessible health care systems and because of the cumulative effect of untreated pre-natal and post-natal diseases, poverty results in a generally poor state of health;<sup>29</sup> (3) conditions of poverty increase exposure to particularly debilitating diseases, e.g., tuberculosis, malaria, hepatitis, respiratory, and parasitic and diarrheal disease, which in turn (in conjunction with generally poor health) impact susceptibility to HIV transmission/infection;<sup>30</sup> and (4) even if the general degradation of health does not increase susceptibility to HIV transmission/infection, the prevalence of untreated STDs and other genital infections/lesions substantially increases the risk of sexual transmission of HIV.<sup>31</sup> In sum, poverty creates poor health and untreated poor health, particularly reproductive health, increases vulnerability to HIV infection.

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<sup>27</sup> A recent Statistics SA report entitled *Measuring Poverty in South Africa* (2000) reports that a majority of residents live below the poverty line, that nearly a third of the population lives in shacks or huts, that more than half of the population does not have a tap inside their dwellings and that twelve percent of households do not have any toilet facilities. Being black, being a woman, and living in a rural community are highly predictive of being poor. Similarly, estimates of unemployment in South Africa range as high as 40%, though some number of these formally unemployed do work in the informal economy. Despite these alarming statistics from South Africa, it is important to remember that South Africa and Botswana are the two most affluent countries in sub-Saharan Africa.

<sup>28</sup> Paul Farmer, *Infections and Inequality: The Modern Plague* (1999); Jim Yong Kim et al., *Dying for Growth: Global Inequality and the Health of the Poor* (2001). “In my work on African AIDS, statistical analysis shows that HIV prevalence is highly correlated with falling calorie consumption, falling protein consumption, unequal distribution of income, and other variables conventionally associated with susceptibility to infectious diseases, however transmitted.” Eileen Stillwaggon, *Determinants of HIV Transmission in Africa and Latin America*, 5 S.A. J. of Economics 68 (Dec. 2000). According to Stillwaggon, “malnutrition and parasitosis ... endemic in poor countries ... have long been recognized as depressing immune function,” undermining epithelial integrity and the production of B and T killer cells. *Id.* Micronutrient deficiencies are also important, particularly Vitamin A, which is essential to epithelial integrity in the genital tract, the major route of HIV infection. *Id.* For an extended discussion of the role of malnutrition in HIV prevalence, see Eileen Stillwaggon, *HIV/AIDS in Africa: Fertile Terrain*, 13-18 (draft 2000).

<sup>29</sup> Farmer, *supra* note \*, at 266.

<sup>30</sup> Parasite infection is particularly debilitating because it robs the host of nutrients and chronically triggers an immune response, impairing capacity to resist other infections. Eileen Stillwaggon, *HIV/AIDS in Africa: Fertile Terrain*, 10-11 (draft 2000). The effect of reduced general health on the actual transmission of HIV is primarily based on conditions that facilitate the transmission of bodily fluids from an infected person to an uninfected person. For example, because poor nutrition and poor health are associated with reduced mucous production and more break down in epithelia tissues, and thus “drier” sex, it seems probable to some researchers that there is a causal relationship of poor nutrition with heterosexual transmission. Likewise, open skin exposure to weeping wounds and disuse of global precautions can facilitate accidental transmission in non-sexual encounters as can needle-sharing in IV drug use. Finally, evidence exists that some vertical transmission of the disease occurs mother-to-child during the traumas of childbirth and in some circumstances from breast-feeding. Transmission from breast-feeding is exacerbated when the infants diet includes formula, water, or any other non-breast milk food that can degrade the mucosal integrity of the infant’s digestive system.

<sup>31</sup> Clearly STD’s that produce genital lesions are a major co-factor in sexual transmission of HIV, Stillwaggon, *supra* note \*, at 11-13, as are sexual practices that create micro-tears in mucosa, i.e., so-called “dry sex” (produced by use of herbal astringents or other chemicals) and anal sex.

All of the poverty-related poor health and poor health care factors that go into increased susceptibility to HIV also affect the speed with which it progresses to full-blown AIDS and to death by opportunistic infection.<sup>32</sup> In particular, poverty-related lack of access to medical treatment, either to reduce viral load or to prevent and treat opportunistic infections, results in a lower quality of life, more rapid development of AIDS, and more rapid demise for poor people living with HIV/AIDS. For example, people infected with HIV, who also have latent tuberculosis are 30-50 times more likely to develop active TB. Similarly, ten percent of HIV infected persons develop cryptococcal meningitis, a fungal infection which leads inexorably to an extremely painful death within 30 days unless treated with powerful fungicides.

### *Social/Economic/Racial/Gender Effects*

Poverty affects HIV/AIDS not simply through *poor health* and *poor health care effects*, it also impacts the incidence of HIV through *social/economic/racial/gender effects*. These effects are myriad, particularly given the historical effects of colonialism/neo-colonialism, slavery/apartheid, misogyny/patriarchy. For example, the "logic" of slave, colonial, and apartheid economies was to disrupt family structures, to displace and concentrate agricultural, mining, and industrial workers into squalid, single-sex living conditions, and to foster migration between regions and unplanned urbanization of heretofore predominately rural societies. These conditions were forced on African communities and justified through racism, a racism that rationalized the even greater disruptions and dislocations of slavery and apartheid.<sup>33</sup>

These colonial/economic/racial effects combine with "imperial" and "traditional" gender inequalities to expose rural women and women-at-home to the dangers of AIDS.<sup>34</sup> In particular, there has been increased sexual exploitation of women through formal and informal prostitution,<sup>35</sup> fueled in part by the increasingly impoverishment of women in rural and township communities.<sup>36</sup> Moreover, the disruption of traditional family structures, traditional cultural mores, and communal forms of regulating sexual relations may also have resulted in an increase

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<sup>32</sup> Estimates vary in developing countries on the latency period of HIV, ranging generally from 7-9 years depending on other health factors. See UNAIDS 2000 Report, *supra* note 2, at \*. This is several years faster than in the developed world. However, the development and progress of fatal opportunistic infections is much faster, currently estimated to be one year only. *Id.*

<sup>33</sup> Ronal Bayer and Mervyn Susser, *In South Africa, AIDS and a Dangerous Denial*, The Washington Post (April 20, 2000).

<sup>34</sup> Men returning home from work sites and urban areas where they became infected spread HIV to their spouses and other sexual partners. Since the concentration of poverty is even worse in the countryside and because health and living conditions are worse as well, rural women are particularly prone to infection. After a certain period of time, some of the rural infection rates become even higher than the urban/township rates.

<sup>35</sup> Too much emphasis on female prostitution is problematic when it is offered as the major explanation for the transmission of HIV. Clearly, poor women are driven to prostitution and to performing unsafe sex for a premium price. Clearly, as well, prostitution concentrates the infection and thereby facilitates the spread of the virus to uninfected sexual partners, both to the men who frequent prostitutes and to those men's future sexual partners. There are few good studies that estimate the relative effect of prostitution on the spread of HIV. No matter how big a role sex work plays in the epidemiology of the disease, prostitution in Africa should be contextualized within the legacy of apartheid, gender oppression, and colonialism, particularly their disruptions of family structures, sexual dynamics, and places of residence.

<sup>36</sup> Like poverty everywhere, poverty is becoming more feminized in southern Africa as well. For example, in South Africa, approximately 74% of women live in poverty. The causes of this feminization are complex, but they include the legacies of apartheid that relegated women to barren homelands with little arable land and no other means of production except subsistence farming and home care of children and elders. Women in the countryside are highly dependent on meager remittances from men and other relatives working at low wages in the formal economy.

in the number of sexual partners for both sexes as well as increased incidence of sexual violence<sup>37</sup> and sexual exploitation of younger women and girls.<sup>38</sup> In addition, because of gender inequality and traditions of patriarchy, women have limited power to negotiate safer sex with their sexual partners inside or outside of marriage.

These combined social factors have been highlighted in various studies that emphasize the role of migration in HIV transmission,<sup>39</sup> as well as the role of the transportation industry,<sup>40</sup> the mining industry,<sup>41</sup> the hostel system, and the military<sup>42</sup>. As previously discussed, these social factors have led to the disproportionate concentration of HIV infection in the Black African community and to the greater vulnerability of women to HIV infection.

Poverty also produces *educational/informational* effects that exacerbate the spread of HIV. Poor children in southern Africa often receive little or no science/health education and what education they do receive is post-Bantu<sup>43</sup> at best. Likewise, basic adult education is virtually non-existent.<sup>44</sup> What limited educational opportunities that exist are being undermined by the pandemic itself, both because of losses of teachers<sup>45</sup> and because of the unaffordability of even minimal school fees for a new and growing generation of AIDS orphans.<sup>46</sup> Thus, in less developed sub-Saharan African countries, many people do not have a medical/scientific world-view that prepares them to understand the causes and epidemiology of HIV. Moreover, because

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<sup>37</sup> South Africa is regrettably reported to be the rape and sexual violence capital of the world. HIV Insite, *supra* note 8, at 3-4.

<sup>38</sup> There is some evidence that some South Africans are having sex at younger and younger ages, but in particular there is evidence that younger women and girls are being forced/enticed into sex with older males, including teachers. Human Rights Watch, *supra* note \*. Thus, the demographics of infection among young people in South Africa is that women become infected at a significantly younger age than their male peers by an average of 5-10 years.

<sup>39</sup> Joseph Collins & Bill Rau, *Aids in the Context of Development*, 8-13 and sources cited (UNRISD Programme on Social Policy and Development, Paper No. 4 Dec. 2000). Rates of infect among men and women who migrate in and out of country are two to three times higher than their non-migrating peers.

<sup>40</sup> Truckers use of prostitutes and the substantially higher rates of HIV infection rates in transportation corridors has been offered as a major factor in the inter-regional spread of AIDS in Africa and in the spread from truckers to the sexual partners back home in rural communities.

<sup>41</sup> The mining sector is a particularly poignant example of an industries where men are lured from the countryside, housed in large numbers in hostels, denied access to their families for as many as 50 weeks out of the year, and thus especially likely to have multiple sexual partners and sex with prostitutes.

<sup>42</sup> The military HIV infection rates in the northern provinces of South Africa have been reported astoundingly high, with estimate ranging from 50-90%.

<sup>43</sup> Bantu education, as a term of art, is an education “fit for water carriers and for wood-carvers” – in other words, fit only for a subordinated community denied the benefit of literacy, numeracy, and scientific knowledge. Coincidentally, Bantu education was imported to South Africa from the Jim Crow South early in the 20<sup>th</sup> century. One consequence of Bantu education is that many African teachers have received very little education themselves. In rural schools, many of the teachers did not complete high school let alone attend college. While in school, they received no training themselves in health or science.

<sup>44</sup> Less than 50% of South Africans have received more than a primary education.

<sup>45</sup> Teachers in southern Africa are paradoxically experiencing above average infection rates and are beginning to die faster than they are being trained. Because of younger and younger initiation in sexual activity, typically between age 13 and 15, life lessons about HIV/AIDS will need to be taught effectively to very young children. *Lessons in Dying*, The Teacher – Daily Mail & Guardian, Sept. 11, 2000.

<sup>46</sup> The number of AIDS orphans is truly frightening with estimates of over 13 million in Africa by 2001 and an estimate of 40 million by 2010. Although South African families show an incredible willingness to take in AIDS orphans (in one survey 74% are willing with no government report and 86% with some government support), there is still an alarming increase in homeless children and children headed households. These children often lack the economic means and secure social structures to attend school.

of low literacy rates, multiple home languages,<sup>47</sup> and poor access to telecommunications and print media, many people in developing countries do not have access to the official AIDS prevention message. Because of customary belief systems, social taboos against talking about sex, disinformation from some traditional healers,<sup>48</sup> and bizarre myths about HIV/AIDS,<sup>49</sup> people in poor communities frequently do not understand the most basic means to protect their own health and the health of others.

#### FURTHER CONTEXTUALIZING THE PANDEMIC – HOW RACISM AND GLOBALIZATION EXACERBATE POVERTY AND AIDS

Because of its *ideologies of racial and class/regional supremacy*, the First World, particularly the U.S. government and corporate elites, make the above effects of poverty worse first by callous and knowing neglect of the HIV/AIDS crisis in Africa and second by imposing neo-liberal policies that exacerbate rather than relieve poverty. With respect to neglecting the AIDS crisis, the U.S. and European community have had important information about HIV/AIDS since the mid-1980's and plausible means of treatment since the early 1990's and yet both have done little or nothing to address the growing pandemic in Africa. Instead the U.S., and its World Bank, International Monetary Fund, and World Trade Organization allies, have used debt policy, trade policy, international currency market policy, structural adjustment policy, and intellectual property regimes to guarantee profits to the pharmaceutical industry and stability for U.S. financial and export/import industries at the expense of hundreds of millions of Africans.

#### *Perpetuating a Culture of Neglect*

The Central Intelligence Agency had notice of the impending African AIDS pandemic as early as 1987 and began studying it in earnest in 1990. In an Interagency Intelligence Memorandum 91-10005 entitled “The Global AIDS Disaster,” the authors projected 45 million HIV infections by 2000 – inexorably fatal, the great majority in Southern Africa.<sup>50</sup> This prediction, though surprisingly close, was actually an underestimate – 53 million people had contracted HIV by the year 2000, 19 million of whom have died. When the CIA Report was first released, it was either ignored or trivialized. One militarist is reported to have quipped, “Oh, it will be good because Africa is overpopulated anyway.”<sup>51</sup> The World Bank apparently agreed, releasing a June 1992 Report that stated, “If the only effect of the AIDS epidemic were to reduce

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<sup>47</sup> South Africa has eleven official languages and many other unofficial languages as well. Most media and public billboard AIDS prevention messages are in English, a language which many South Africans cannot read.

<sup>48</sup> Rural and tribal South African rely substantially on traditional healers (Sangomas) both for spiritual and indigenous medical cures for their illnesses. Many of these healers are highly skilled in the use of medicinal plants and are very concerned with the medical and spiritual well-being of their patients. Moreover, some traditional healers are connecting with mainstream medical providers for the first time to better understand HIV/AIDS and to provide more appropriate medical support and advice about transmission, diet, and healthy living. However, there are clearly Sangomas who have promised and charged for charlatan cures of HIV and there are reported incidents of unnamed Sangomas recommending that men sleep with virgins as a cure for AIDS. Nonetheless, whatever hope there is for an effective AIDS prevention and treatment campaign in South Africa depends in substantial part on involvement and collaboration with traditional healers and with other leaders in traditional communities.

<sup>49</sup> In addition to myths about sleeping with virgins, there are reports of myths about sleeping with “fat” women instead of “skinny” women as well as many myths about the danger posed by close association with people living with HIV/AIDS, not dissimilar from the early fear myths in the U.S.

<sup>50</sup> Barton Gellman, *The Belated Global Response to AIDS in Africa*, Washington Post A1 (July 5, 2000).

<sup>51</sup> *Id.*

the population growth rate, it would increase the growth rate of per capita income in any plausible economic model.”<sup>52</sup>

Similarly, the World Health Organization, ineffectual by most standards in stemming the pandemic, but highly effective in predicting it, foretold tens of millions of deaths by 2000.<sup>53</sup> Despite this prediction, most of the 1990’s was characterized by indifference, petty infighting, and procrastination at the WHO and in other UN structures; it wasn’t until 1996 that the UN even succeeded establishing its UNAIDS program. The moment UNAIDS was established, however, its partners, the World Bank, WHO, and UNICEF, dropped their funding to AIDS from \$225 million to \$40 million.<sup>54</sup>

The most telling measure of the First World neglect is financial. The first U.S. budget submitted after the 1991 CIA report appropriated only \$124.5 million for all overseas AIDS control, only a portion of which went to Africa.<sup>55</sup> In a recent study, Amir Attaran and Jeffrey Sachs of Harvard’s Center for International Development found that between 1996 and 1998, financial aid from all rich countries to sub-Saharan Africa for AIDS control projects was between \$69-140 million annually. Since the late 1980’s, absolute aid levels dropped relative to HIV prevalence and recently stood at only \$3 per HIV-positive person.<sup>56</sup>

### *The Impacts of Globalization*

It would, of course, have been bad enough if southern Africa were to merely have suffered the insult of First World neglect. However, at the same time that world powers were ignoring the impending AIDS catastrophe through their political structures, their economic structures, through neo-liberal policies that have come to be called globalization, have caused disastrous injury to the general health of African economies and to the well-being of public health systems in particular. Although this is not the place to document the entire story of failed neo-colonial “development” and globalization in Africa, it is appropriate to trace some of the key aspects of neo-liberal policy that have intensified the AIDS crisis. These include: (1) maintaining colonial patterns of ownership; (2) creating crushing debt through aid and loan policies; (3) deforming economies towards exploitation of natural resources and production of low-cost exports and importation of high-cost finished goods; (4) liberalizing currency exchanges and financial markets resulting in currency devaluations, market volatility, and net outflow of capital; (5) enforcing structural adjustment policies, including (a) fiscal austerity and reduced government spending particularly in health care and (b) privatization and commodification of public resources, goods, and services; and (6) increasing income inequality and feminizing poverty.

First, no story about the impact of globalization can start without first recognizing that most of the productive capacity in many African countries, South Africa in particular, resides in the portfolios of former colonial masters. Although local elites have been given managerial and window-dressing positions and occasional junior partner status so as to create a narrow strata of local elites who help to manage the status quo, the vast majority of productive capacity in Africa is owned by multinational corporations and Africa’s colonial heirs. Thus, wealth continues to be extracted from Africa literally and figuratively, from the mines, from the farms, and from the sweat of Black labor.

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<sup>52</sup> *Id.*

<sup>53</sup> *Id.*

<sup>54</sup> *Id.*

<sup>55</sup> *Id.*

<sup>56</sup> Amir Attaran & Jeffrey Sachs, *Defining a Refining International Donor Support for Combating the AIDS Pandemic*, 357 *The Lancet* 57 (2001).

Second, Africa has been buried in debt starting in the late 1960's, culminating with \$227 billion in debt by 2000. Although much of that debt was at one point private debt, frequently debt of private industry to private banks used in the capitalization of productive capacity, the debt increasingly became multilateral and bilateral, debt owed by African governments to individual governments and/or to the World Bank and International Monetary Fund. As the value of export products plummeted in the 1980's and as the costs of luxury and capital imports increased, African countries needed to borrow more and more money to refinance their foreign currency reserves. Similarly, as the World Bank lent money to governments to build physical infrastructure appropriate to an import/export economy and as First World governments bilaterally lent money to finance purchase of excess goods, military and non-military, from same-nation producers, the African debt burden became more and more bloated. Fundamentally, Africa is now permanently indebted as a result of an inherently imbalanced pattern of trade between the under-priced agricultural and pre-industrial economies of the South and the overpriced industrial economies of the North.<sup>57</sup>

Paying this old debt off is particularly problematic since so little of it resulted in increased productive capacity, job creation, or wealth redistribution.<sup>58</sup> Not only was loan money used to buy expensive Western consultants, questionable showcase infrastructure projects, e.g., hydro-electric dams, and Western luxury imports, a great deal of it was given to undemocratic, racist, and corrupt governments that were proxies to foreign business interests and lackeys to the great powers during the Cold War. Since these debts incurred by old elites did not result in economic benefit to the poverty-stricken masses, it is doubly burdensome to make the current poor pay them off.

As stated, sub-Saharan African countries owe the IMF, World Bank, and rich countries more than \$227 billion dollars, with an annual debt servicing charge of nearly \$14.5 billion, equaling 5% of GDP and 15% of export earnings. As a consequence of this enormous debt burden and usurious repayment schedule, many southern African countries spend more on debt repayment than on public health. For example, Uganda spends 1.6 percent of GDP on health and 2.4 percent on debt service; Zimbabwe 3.4 percent and 10.3 percent; and Zambia 3.2 percent and 9.8 percent. In South Africa, the debt load is not just loans from international lenders, it is also internal debt owed by the current government to internal financial institutions and public pensions plans, a burdensome and odious debt that capitalizes the legacy of apartheid.

The Jubilee 2000 Campaign and many other activist groups have campaigned for cancellation of this debt.<sup>59</sup> Despite limited promises of debt relief from the World Bank (Highly Indebted Poor Country Initiative) and the G-8, only minimal debt has been forgiven and to date in only a handful of countries.<sup>60</sup> Jubilee 2000 South Africa and South Africa's Alternative Information and Development center are simultaneously launching more aggressive Apartheid Caused Debt and Odious Debt campaigns, calling not only for debt forgiveness but for reparations.<sup>61</sup>

Third, the general effect of international trade policy, all too readily accepted in South African and other African countries, has been to dismantle rural subsistence economies and multi-sectorial economies in favor of predominantly import/export-oriented economies.<sup>62</sup> Thus, it has

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<sup>57</sup> See Francisco G. Pascual, Jr., *The Development and Historical Context of the Debt Crisis* (1999) ([http://jubileesouth.net/summit/19991119/address\\_pascual.html](http://jubileesouth.net/summit/19991119/address_pascual.html)) (1/05/01).

<sup>58</sup> Sean Flynn, *A Program for Democratic Development: A Savings and Investment Policy for South Africa* (draft 2000).

<sup>59</sup> See Jubilee South, *South-South Summit Declaration: Toward a Debt-Free Millennium* (Nov. 21, 1999).

<sup>60</sup> Drop the Debt, Draft – Debt Cancellation to Combat the Global HIV/AIDS Pandemic (Dec. 10, 2000).

<sup>61</sup> Alternative Information & Development Center, *Apartheid Caused Debt Campaign - Challenging Apartheid's Foreign Debt* (<http://www.aids.org.za/adc-summary.html>) (1/5/01).

<sup>62</sup> Patrick Bond, *Can Thabo Mbeki Change the World? Strategies, Tactics and Alliances Towards Global Governance* (The Frantz Fanon Inaugural Memorial Lecture, University of Durban-Westville School of

become increasingly impossible for persons in the countryside, with minimal access even to marginal land, to make a living.<sup>63</sup> Instead, agricultural economies have been restructured towards a narrow range of export farm products, many of which, like timber in South Africa, are destructive of fertile land and heavy users of scarce water resources. People, particularly young men, dislodged from the countryside, have migrated in mass to the cities, where rumors of jobs far outweigh their actuality. Even here, in urban contexts, the new industries are export oriented and increasingly capital intensive. It is an environment with few jobs, but one with decreased social and familial stability. It turns out to be a perfect breeding ground for AIDS.

Fourth, as if external ownership, crippling debt, and liberalized trade policy were not disruptive enough, globalization has also liberalized currency exchanges – causing capital flight – and forced currency devaluation – typically 50% as an initial adjustment – both with horrendous economic effects. One of the most significant aspects of the current neo-liberal regime is the greatly expanded international currency exchange market and the proliferation of national and regional liquid asset markets. The sale and movement of import/export goods in the world's markets is considerably less important to finance capital now that it used to be. In contrast, the volume of international currency exchange/speculation and financial market investment has increased thirty-fold in the last 30 years. Thus, international finance capital has become more interested in making money off of currency markets and capital markets, especially stock exchanges, than it is in investing in productive capacity.<sup>64</sup> This new focus on financial rather than productive investment has led to speculative bubbles in currencies and financial exchanges, with a temporary influx of external capital, followed, almost inevitably, by currency and market crashes such as those in Asia's Tiger economies.

Because of international (external) and national (internal) currency flight to more stable and profitable currencies, the money available for productive capacity investment in Africa is greatly decreased, down 50% in South Africa in 2000. Similarly, as a result of devaluation systematically engineered by the IMF, such as the 300% devaluation of the South African rand in the last seven years, African exports are worth even less (though more price competitive) and First World imports, including pharmaceuticals, cost even more. At the same time that import costs increase and basic-goods export income falls, the foreign debt, calculated in local currencies, multiplies. Thus, the vibrant U.S. economy and stock market boom of the 1990's, to a large extent, was "purchased" as a result of marketplace misery in the Third World.<sup>65</sup> Low-cost imports into the U.S. keep rates of inflation low, which eased Federal Reserve Board anti-inflation policy. These policies resulted in significant wealth effects in the U.S., at least for the top tier of the economy. Conversely, prices African countries have risen dramatically, and life-saving imports, including HIV/AIDS medications, have become even more expensive.

Fifth, the debt and balance-of-payment crises in Africa, which consolidated debt within multilateral institutions, set the stage for infamous structural adjustment policies that have further deflated and destabilized African economies. These structural adjustments, imposed by the IMF and the World Bank as a condition of extending and refinancing African debt, invariably included

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Governance 17 Aug. 2000); Patrick Bond, *Elite Transitions: From Apartheid to Neoliberalism in South Africa* (2000); Patrick Bond, *Cities of Gold, Townships of Coal: Essays on South Africa's New Urban Crisis* (2000).

<sup>63</sup> Collins & Rau, *supra* note 30, at 18.

<sup>64</sup> Noam Chomsky, Speech on Globalization, MIT (Sept. 26, 2000).

<sup>65</sup> The effect of currency devaluation and cheap imports on inflation rates in the U.S. is much more important vis a vis our major trading partners, Asia, than Africa. Since African imports play such a minor role in the U.S. economy, it would be misleading to suggest that the U.S. stock market boom is strongly tied to devaluation in Africa. What is more true generally is that low prices on raw materials and low technology goods, combined with devaluation, do help subsidize U.S. prosperity. It is also fair to note that the reverse effect of import/export prices on GDP and price stability may be proportionately much worse in African countries than in the U.S. Email from Kieran Honderick, economist, September 14, 2000.

two phases. The first phase required macro-economic stabilization via currency control deregulation/devaluation, price stabilization through reduced real wages and consumption, and budgetary austerity including a mandatory 3% cap on deficit spending. Phase two required trade liberalization, tax reform transferring tax burdens from businesses to workers and consumers, privatization/commodification of government services and assets, including user fee policies, and liberalization of labor laws including non-indexing of wages.<sup>66</sup> Thus, at the same time that the global powers were using structural adjustment policies to force reductions in social spending, including social spending on public health, on education, and on HIV/AIDS prevention and treatment, they were imposing user fees on medical visits, charging for condoms, and retailing medicines. World Bank and IMF “un”healthy SAPs, such as cost-recovery or fee-for-services, have resulted in dramatic lower attendance in STD clinics in Kenya and in reduced condom use in Zimbabwe.<sup>67</sup>

Sixth, the net effect of structural adjustment, debt, and trade policies mandated by the North has been greater income/wealth inequality and the feminization of poverty in the South.<sup>68</sup> These policies have to some extent helped to create a thin layer of black African elites, but good times have clearly not trickled down to the poor in general and women in particular.<sup>69</sup> In the new South Africa, there are fewer rather than more new jobs than there were at the end of apartheid. Similarly, income inequality too has grown so that South Africa<sup>70</sup> is now the most income inequitable country in the world. As economic inequality increases and as women are increasingly forced into poverty, studies show that HIV infection rates *invariably* increase.<sup>71</sup> Thus, it is no exaggeration to argue that globalization is a leading cause in the African AIDS pandemic, contributing not only to its severity but confounding its cure.

### *Corporate Complicity*

The relatively impersonal and indirect forces of globalization described above are matched by the direct actions of major multinational corporations operating in Africa. Although

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<sup>66</sup> See Pascual, *supra* note \*; Eric Toussaint, *From North to South: The Debt Crisis and Structural Adjustment Policies* (trans. Vicki Bialut, 2000) ([http://jubileesouth.net/documents/discussions/debt\\_crisis\\_saps.html](http://jubileesouth.net/documents/discussions/debt_crisis_saps.html)) (12/12/00). As a matter of institutional competence, the IMF and the World Bank play two different roles. The IMF is typically involved in policy negotiations regarding the exchange rate, currency exchange, financial market deregulation, and the overall budget deficit. The World bank micro-manages government spending and infrastructure investment.

<sup>67</sup> See Collins & Rau, *supra* note 30, at 18 and sources cited; Sanjay Basu, Kedar Mate & Noor Jehan Johnson, *Poverty's Pathologies: Global Inequalities and the Lives of the Destitute Sick 3* (Draft 9/5/00).

<sup>68</sup> Female poverty is intensified as a result of structural adjustment policies of the World Bank, International Monetary Fund, and World Trade Organization, all of whom favor the creation of low-wage export industries at the expense of broad-based and sustainable economic development and local micro-enterprise, policies which would produce more equitable employment opportunities for women. As a result, not only are women poorer, they live in disrupted family structures, and are often forced into high risk, survival sex work. Collins & Rau, *supra* note 30, at 13-15, 19-21.

<sup>69</sup> South Africa's infamous GEAR policy has been an abysmal failure at job creation, having resulted in the loss of nearly a half a million jobs in the formal sector, with few new jobs taking their place. In addition, so-called labor flexibility policies have resulted in reduced job protections, wage stagnation, and attacks on organized labor.

<sup>70</sup> Income inequality in South Africa has actually increased as a result of its neo-liberal economic policies, many of which were mandated by the forces of globalization. Roy Cokayne, *Inequality Increasing, Says Poverty Report*, S.A. Business Report (Sept. 8, 2000).

<sup>71</sup> See Farmer, *supra* note \*, at 265; A World Bank Policy Research Report, *Confronting AIDS: Public Priorities in a Global Epidemic*, Chapter 1, subsection 3, p. 1 (Oxford University Press, Revised edition 1999) (<http://www.worldbank.org/aids-econ/confront/confrontfull/chapter1/chp1sub3.html>) (11/01/2000).

multinational corporations have "responsibilities" as global citizens and as employers to initiate and support efforts to alleviate the HIV/AIDS pandemic, particularly among their employees, they are also individually and collectively "responsible" in another sense – they have engaged in practices and policies that have intensified the pandemic. Unfortunately, there are multiple examples of business practice, individual, collective, and by proxy, that amount to **corporate complicity** in the deepening crisis in developing countries, particularly Africa:

- Multinational corporations have frequently relied on a migrant, all-male workforce and have made no provision for housing families or for promoting conjugal relations. During, and after, systems of apartheid and colonial rule, men have been housed in cramped hostels for months at a time, often with leave to visit home only once a year for a few weeks. Naturally, these conditions, and the poverty of women, resulted in intimacy with sex workers and a high incidence of STD's and HIV infection that were subsequently transmitted to sexual partners back home.
- Multinational corporations have promoted peri-urban industrialization, invested extensively in export-oriented commodity production and natural resource extraction, and favored capital intensive manufacturing all of which have negatively affected employment and rural economies so as to increase vulnerability to HIV. These policies have also negatively impacted food security and nutrition thereby increasing susceptibility to HIV transmission.
- Multinational corporations have insisted on the development of transportation infrastructures, but have made no provision to prevent or reduce HIV transmission along truck routes, at sea ports, and along other systems of transportation. Similarly, multinational corporations have insisted on the development of mega hydro-electric and communication projects but have not provided for the HIV security of its transient workforce.
- Multinational corporations have pursued tax rate reductions, tax concessions, and other forms of tax avoidance that have permitted them to under-fund social welfare and public health systems that might have responded more appropriately to the pandemic.
- Multinational corporations and their investment partners have insisted on fiscal restraint, reductions in public sector employment, and privatization schemes that have led to the reduction of public services particularly health services for poor people. Corporate proxies at the World Bank and IMF have insisted on structural adjustment policies such as fee-for-services that have negatively impacted health care affordability and utilization.
- Multinational corporations, through their multilateral partners, have insisted on currency and financial market flexibility that has frequently resulted in a net outflow of profits and investment away from developing countries.
- Multinational corporations have resisted demands that they provide medical insurance, medical benefits, and medical treatment to their workforce that might result in a better general state of health and thus resistance to HIV transmission.
- Multinational corporations have neglected to provide medical coverage or treatment of HIV and opportunistic infections for direct and indirect corporate employees and for their family members.

- Multinational corporations have neglected to institute wage continuation programs for employees disabled by AIDS.
- Multinational corporations have historically failed to provide employee education about sexual health and safe sex, have failed to offer confidential voluntary HIV counseling and testing, and have failed to provide male and female condoms to their workforce.
- Multinational corporations have stigmatized, discriminated against, and fired workers who are HIV positive and have violated rights of privacy with respect to confidential medical information.

## CONTEXTUALIZING THE ROLE OF THE PHARMACEUTICAL INDUSTRY IN THE AFRICAN AIDS PANDEMIC

The multiple impacts of globalization on African economies and the African AIDS crisis have been serious enough, but certain impacts have been much more direct, particularly those engineered by the truly gigantic pharmaceutical industry, whose worldwide sales in 1999 were \$315 billion, more than the gross domestic product of all Southern African Development Community countries combined.<sup>72</sup> When governments and medical providers in Africa have looked for viable HIV treatment options, they have repeatedly been confronted with industry demands that developing nations respect recently imposed international intellectual property regimes granting 20-year patents on medicines and that they buy HIV/AIDS medications at astronomical costs, far above the actual costs of production.<sup>73</sup> When African governments resist paying these unaffordable prices and instead threaten to use parallel importation schemes to buy cheaper versions of patented drugs in other countries<sup>74</sup> or threaten to use compulsory licensing to produce or import generic equivalents<sup>75</sup> with only modest licensing fees to patent holders, the U.S. government historically retaliated with threats of trade sanctions and economic isolation.<sup>76</sup> To supplement the threat of trade sanctions, in 1998, the pharmaceutical industry filed suit against new South African legislation designed in part to permit price transparency, substitution of off-patent generic medicines by pharmacists, and the parallel importation of cheaper life-saving

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<sup>72</sup> Similarly, the combined worth of the five largest companies is twice the GDP of all of sub-Saharan Africa.

<sup>73</sup> The marginal production costs of HIV/AIDS medications is often a tiny fraction of their market price. Full market prices are astronomical absolutely, but especially when compared with the ability of poor countries to pay using devalued currencies. Nonetheless, pharmaceuticals frequently justify their high drug prices because of research and development costs, even though many of the most significant HIV/AIDS medications have been developed through the public sector/academic research and even though many of the industry's R&D costs of in fact product differentiation and indirect marketing costs. As an industry, pharmaceuticals spend far more on marketing than they do on R&D. Even so, despite R&D and marketing costs, the industry is extraordinarily profitable. The eleven largest pharmaceuticals are reported to have had nearly 27 billion dollars in profits in 1999.

<sup>74</sup> Many patented drugs are sold substantially cheaper in one country than another creating a price incentive to do comparison shopping internationally. For example, drug prices are often much cheaper in Canada than in the U.S.

<sup>75</sup> Where generic manufacturing facilities have been permitted to develop, generic HIV/AIDS medications often cost 10% or less than the patented drug price. Currently, India, Thailand, and Brazil have generic production underway.

<sup>76</sup> For a detailed discussion of this history, see Patrick Bond, *Globalization, Pharmaceutical Pricing and South African Health Policy: Managing Confrontation with U.S. Firms and Politicians*, 29 Int'l J. Health Services (#4 1999).

medicines.<sup>77</sup> Thus, before exploring recent developments that promise to make certain HIV/AIDS medicines cheaper and more accessible, the prior history of monopoly pricing, trade bullying, and a medicines embargo – best characterized as pharmaceutical apartheid – must be explored first. Only then can we fairly evaluate the pharmaceutical industry’s current efforts to save face.

### *Industry’s Neglect Patterns Governmental Neglect*

Anti-retroviral medications that suppress the load of HIV virus in infected persons, and thus reduce susceptibility to opportunistic infections, have been developed and widely used in the First World since the early 1990’s. Likewise, multiple medications have been developed that prevent and/or treat the opportunistic infections that eventually kill persons with full-blown AIDS. Much of the research into these anti-HIV drugs has been subsidized by government, though there are still significant research and development costs in bringing new drugs to market. These medical discoveries are protected by patents held by the pharmaceutical industry which is now among the most profitable industries in the world. These patents permit the pharmaceutical companies to set their own price for the medications at a price far above actual production cost, although the price charged is somewhat responsive to market competition and thus varies significantly among countries. Nonetheless, routine, triple-dose anti-retroviral regimes are extremely expensive, costing \$10,000-\$15,000 per year in the United States. In contrast, Doctors Without Borders suggest that with economies of scale anti-retrovirals could be sold for as little as \$200 per person per year, 2% of the current First World price.<sup>78</sup>

In 1991, following the first of the key anti-retroviral discoveries, chief executives of eighteen major pharmaceutical companies arrived at WHO’s Geneva’s headquarters where they were introduced to the magnitude of the AIDS crisis in the developing world and asked for flexibility in pricing their new anti-retroviral medicines. Over the next two years, the industry responded explicitly to requests for discounted or tiered prices by championing its research and development mission and by questioning Africa’s medical infrastructure. Implicitly, even though Africa represented only 1% of worldwide pharmaceutical sales, the industry was concerned about reimportation of discounted drugs into the overpriced First World market and about consumer/political backlash if the discounts drew attention to bloated profit margins on AIDS and other medicines.<sup>79</sup> In the end, the industry did nothing during the last decade of the 20th century. Other than through selected and highly questionable drug trials<sup>80</sup> or through occasional but highly

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<sup>77</sup> The Pharmaceutical Manufacturers Association of South Africa and forty-one major pharmaceutical companies filed suit against the Medicines and Related Substances Control Amendment Act (Act 90 of 1997) shortly after its passage, alleging that the act infringed patent rights. Although the suit was suspended in 1999 pending negotiations, the Association resumed active litigation on August 1, 2000. The trial was scheduled to start on March 5, 2001, but was postponed because of the successful legal intervention of the Treatment Action Campaign. Because of an international protest campaign, the industry dropped its lawsuit on April 18, 2001.

<sup>78</sup> Medecins Sans Frontieres, Campaign for Access to Essential Medicines, *HIV/AIDS Medicines Pricing Report. Setting Objectives; Is There a Political Will*, 18 (July 6, 2000).

<sup>79</sup> Barton Gellman, *An Unequal Calculus of Life and Death*, Washington Post (Dec. 27, 2000) (<http://www.washingtonpost.com/ac2/wp-dyn/A51719-2000Dec26?language=printer>) (1/02/2001).

<sup>80</sup> A discussion and critique of drug company product testing practices is beyond the scope of this paper. However, Africa and other developing countries have become favorite low-cost venues for FDA mandated drug trials. Because of the dense concentration of diseased populations, because of the absence of previous exposures to medicines, because of the ease of obtaining poorly informed consent, because of the reduced safety oversight of governmental agencies, and above all because of lower costs, major pharmaceutical companies are using Africans as the guinea pigs for First World medicines. One of the great ironies of these trends, however, is that a few Africans get short term treatment for long term diseases. After the

publicized research projects and corporate charity events, barely a single dose of HIV/AIDS medicines reached a single Africa consumer except through the normal channel of high profit sales. As a consequence, within the entire continent of Africa, fewer than 1/10 of 1% of people living with AIDS, 30,000 persons only, have had access to the antiviral medicines that now routinely extended life in U.S. and Western Europe.

*The Industry Moves to Secure and Protect Patent Rights Internationally*<sup>81</sup>

At the end of the Second World War, the major economies of the North signed the General Agreement on Tariffs and Trade, a treaty designed to achieve the progressive liberalization of international trade through successive negotiations. The eighth round of negotiations, the so-called Uruguay Round lasted from 1986 to 1994 and ended both with the establishment of the World Trade Organization and the passage of the Agreement on Trade-Related Aspects of Intellectual Property Rights, or TRIPS.<sup>82</sup> Although previous international treaties, particularly the Paris Convention for the Protection of Industrial Property, had attempted to create some control over national patent legislation, there was, prior to TRIPS, a great deal of pluralism in patent regimes between different countries and regions. For example, prior to the Uruguay Round, about 50 countries did not grant any patent protection whatsoever for pharmaceutical products, including both developed and undeveloped countries.<sup>83</sup> A subset of these countries allowed patent protection for pharmaceutical processes but not for patents. Since patent rules in these countries did not foreclose generic production, many of these countries developed robust generic industries that could produce lower cost medicines for local use, frequently at one third the cost of patented drugs.<sup>84</sup>

Accordingly, in the absence of monopoly power, there was a range of pharmaceutical capacity in different countries and a highly diversified industry. Ten countries, all industrial, had a sophisticated pharmaceutical industry with a significant research base. Seventeen nations, twelve industrial and five developing, had a pharmaceutical industry with some innovative capacity. Fourteen nations, six industrial and eight developing, had the capacity to produce both therapeutic ingredients and finished products. Eighty-nine countries, two industrial and eighty-seven developing, had the capacity to formulate finished products only from imported therapeutic ingredients. Sixty countries, fifty-nine of which were developing, were without any pharmaceutical industry.<sup>85</sup> The net effect of this state of industry diversification was that major pharmaceutical companies discovered, tested, and marketed most new medicines in rich economies, but that the medicines were occasionally “finished” or “knocked off” elsewhere thereby building local industries, reducing prices, and easing balance of payment problems in some poorer countries.

Responding to this irritating competition from generic producers, the U.S. and E.U. pharmaceutical industry played a lead role in the negotiation of TRIPS,<sup>86</sup> not only by convincing

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trials, the drugs are frequently withdrawn not just from the drug trial patients, but, because of pricing, the drug are essentially unavailable to African countries. See The Washington Post's Six-Part Series, *The Body Hunters* (Dec. 17-22, 2000) <http://washingtonpost.com/wp-dyn/world/issues/bodyhunters/>.

<sup>81</sup> Most of the information for this section comes from Karin Timmermans and Togi Hutadjulu, *Report of an ASEAN Workshop on the TRIPs Agreement and its Impact on Pharmaceuticals* (WHO 2000) (hereinafter, ASEAN Report).

<sup>82</sup> *Id.* at 5.

<sup>83</sup> *Id.* at 11. In fact, pharmaceutical patents were not uniformly recognized in the First World until late in the 20th century: UK (1949), France (1960), Germany (1968), Italy (1978), Japan (1976), Sweden (1978), Switzerland (1977), and Spain (1992). *Id.* at 18.

<sup>84</sup> OXFAM Great Britain, *Fatal Side Effects: Medicine Patents under the Microscope*, 2 (2001).

<sup>85</sup> ASEAN Report, *supra* note \*, at 20.

<sup>86</sup> OXFAM, *supra* note \*, at 38.

trade representatives to champion its interests, but by direct lobbying during the negotiations.<sup>87</sup> At the end of the day, the industry was ecstatic, with its principal negotiator boasting that the industry had achieved all of its aims, controlling the process and the result.<sup>88</sup> Given its advantage in conducting pharmaceutical research and development (96% vs. 4%), the developed world secured near absolute competitive advantage via the TRIPS Agreement. In the long run, as developing and least developing countries were forced into compliance with TRIPS, the major pharmaceuticals could dismantle or marginalize the generic industry that was previously “pirating” medicines without permission. It is estimated that when TRIPS becomes fully implemented, it will raise drug prices in the developing world by approximately 300%.<sup>89</sup>

### *Key Provisions in the TRIPS Agreement*

The TRIPS Agreement (*see* Appendix A, attached) introduced minimum global standards for protecting and enforcing nearly all forms of intellectual property rights, patents, copyrights, and trade secrets, including those applying to pharmaceuticals. The Agreement covers basic principles, standards and use of patents, enforcement, dispute settlement and multiple other subjects, many of which are tilted in favor of intellectual property owners and against the interests of consumers. Under key provisions in TRIPS, member countries must provide patent protection for a minimum of 20 years from the filing date of a patent application, for any invention, including a pharmaceutical product or process, that fulfils the criteria of novelty, inventive step and usefulness. Although preceding patent-rule pluralism in both the developed and undeveloped world had allowed discrimination between fields of invention, for example by excluding medicines, TRIPS expressly outlawed such discrimination. Similarly, it was no longer permissible to discriminate against imports in favor of locally produced products, thus allowing major pharmaceutical companies to control the *place* of production. Because of TRIPS, the major pharmaceutical producers succeeded in consolidating their monopoly power internationally – they have exclusive rights under Article 28 to exclude others from “making, using, offering for sale, selling, or importing” patented pharmaceutical products or products made with a patented process. In addition, the Agreement has provisions governing: protection of undisclosed information (including clinical test data); actions to readdress anti-competitive practices; protection of trademarks (relevant to generic substitution and combating counterfeit drugs); and enforcement when disputes arise. Even though TRIPS confers strong rights on a patent owner, it allows for certain exceptions, the most important of which, parallel importation, limited exceptions, and compulsory licensing, discussed in later sections.

TRIPS delineates three time-frames that will have a dramatic impact on access to medicines. On the plus side, because TRIPS was not formally ratified until 1995, none of its provisions require that a country extend patent protections retroactively to products discovered before its enactment, unless that country’s legal system already mandated such protection and patent applications had already been filed in a timely fashion. Thus, India, Brazil, and a number of other process-only or no-medical patent countries have continued to reverse-engineer pre-1995

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<sup>87</sup> The pharmaceutical industry has over the last two decades become increasingly influential and powerful in Washington politics. Its lobbyists and industry leaders regularly move on to positions in the U.S. Trade Office and vice versa. In the most recent election cycle, the pharmaceutical industry has spent \$230 million on lobbying and campaign contributions and has one lobbyist for every two members of Congress. Pfizer is one of the leading contributors/lobbyists spending millions of dollars to advance its interests. Public Citizen Congress Watch, *Rx Industry Goes for KO: Drug Companies Spend Record Amount this Election Cycle* (November 2000).

<sup>88</sup> “In the words of Edmund Pratt of Pfizer, ‘Our combined strength enabled us to establish a global private sector-government network which laid the groundwork for what became TRIPS.’” OXFAM, *supra* note \*, at 38.

<sup>89</sup> OXFAM, *supra* note \*, at 2-3.

AIDS medicines and to produce them generically. Moreover, India and Brazil could lawfully export these medicines to other countries where patents are not in force or where compulsory licenses have been issued. Such manufacture and export/import would be fully TRIPS compliant.

TRIPS has complicated the future of producing medicines, however, even where productive capacity and sufficient market size exists and even in countries that are currently producing TRIPS compliant generic AIDS drugs, like Brazil and India, because of its “mailbox” and transitional timelines. Because of transitional periods running from 1996 to 2005/06,<sup>90</sup> TRIPS required a so-called “mail-box” rule whereby developing countries were obligated to establish mechanisms for receiving, processing, and establishing “priority-in-time” for pharmaceutical patent applications. Furthermore, the developing countries had to grant exclusive distribution rights to the patent applicant when certain prescribed conditions were satisfied.<sup>91</sup> Thus, the mailbox rule effectively precludes generic manufacturers in developing countries that do not recognize patents on medicines or product patents from producing “copies” of medicines described in “mailbox” applications. Stated differently, patent applicants have significant and exclusive market advantages with respect to post-1995 discoveries even before the full adoption of TRIPS in developing and least developed countries.

Even more dramatically, the window of opportunity for generic producers in developing and least developing countries to copy on-patent medicines without a license is rapidly closing. By January 1, 2005 or January 1, 2006, all countries seeking membership in the WTO must become TRIPS compliant with respect to their patent regime. By these dates, any generic copy of an on-patent medicine must be produced pursuant to a compulsory license issued under Article 31 or as a limited exception, if applicable, under Article 30.

#### *Industry and U.S. Trade Rep Enforcement of TRIPS*

Even though the industry succeeded in passing TRIPS, it was not content to rest on its legislative gains. The industry became increasingly proactive, both on its own behalf and through its U.S. Trade Representative and governmental proxies, to insist on TRIPS-plus bilateral trade agreements, to threaten trade sanctions, to file or threaten litigation, and to use WTO dispute procedures, all to consolidate and confirm its monopoly power.

#### **Selected Protective Actions**

- Before and since the passage of TRIPS, the U.S. Trade Representative, in bilateral and regional negotiations, attempted to coerce trading partners to adopt TRIPS-plus patent rules that provide even more protection for pharmaceutical products. Currently, in FTAA negotiations, the U.S. continues to press for ultra-strong protection of intellectual property rights.<sup>92</sup>
  - In particular, the U.S. has sought agreements that would reduce rights of parallel importation, compulsory licensing, and readiness to manufacture generic medicines as soon as patents expire.
  - It has also attempted to secure strict secrecy of drug trial and drug registration information which creates barriers for generic manufacturers who otherwise have to duplicate expensive and time-consuming drug tests.
- The U.S. Trade office has routinely used its power under section 301 of the Trade Act to threaten trade sanctions<sup>93</sup> against developing countries that “abuse” or threaten to abuse pharmaceutical patents.

<sup>90</sup> Articles 65 and 66.

<sup>91</sup> Article 70.

<sup>92</sup> Robert Weissman, FTAA Comments from Essential Action, Letter to Office of the USTR, August 22, 2001. <http://lists.essential.org/pipermail/pharm-policy/2001-August/001422.htm> (8/28/01).

<sup>93</sup> Section 301 give the Trade Office broad discretion to threaten and eventually impose trade sanctions against listed countries.

Significant pressure was brought to bear first on Thailand and later on South Africa to “respect intellectual property rights.”<sup>94</sup> This pressure continued on South Africa until late 1999, when ACT-UP’s Africa AIDS demonstrations forced Al Gore and Bill Clinton to revise their platforms.

- In South Africa, U.S. and European drug companies, and their South African subsidiaries, took Nelson Mandela and the South African government to court over their determination to purchase cheaper generic and/or brand name medicines for people living with HIV/AIDS under the Medicines and Related Substances Control Amendment Act No. 90 of 1997. Originally filed in 1998 and supported by U.S. threats of trade sanctions until late 1999, the lawsuit was finally dismissed on April 18, 2001. During this protracted litigation, 400,000 South Africans died of AIDS.
  - The Medicines Act was originally intended to permit South Africa to buy patented or brand drugs wherever they were sold more cheaply – using what is called parallel importation. Although frequently confused with generic importation, parallel importation is importation of a branded drug previously sold on the open market by the manufacturer or one of its authorized licensees. Thus, if the drugs were sold more cheaply in India or in Europe, as frequently was the case, then the South African government could bargain shop abroad.
  - Some activists, and the pharmaceutical association itself, have interpreted the Act as permitting importation of cheap generic drugs, called pirate drugs by the industry, by means of so-called compulsory licenses. Under pressure, the South African government has denied any intent to use the Medicines Act in this way.
- In late 2000, with 25.3 million African lives hanging in the balance, the world's largest and most profitable pharmaceutical company, GlaxoSmithKline, threatened a lawsuit against an Indian generic manufacturer, Cipla, which was supplying cheaper AIDS medicines in Ghana. On Feb. 8, 2001, pharmaceutical representatives said they would protect their patent rights against Cipla's new plan to sell generic AIDS drugs to poor African governments at a huge discount.
  - As it now admits, Glaxo does not have an enforceable patent on its HIV/AIDS medicines in Ghana which did not patent pharmaceuticals at the time Glaxo filed its patent application with a regional patent authority.
  - Cipla is currently manufacturing its HIV/AIDS medicines legally because India is not yet subject to the draconian WTO TRIPS patent regime and its national legislation still does not allow patenting of pharmaceutical products and won't have to until 2006. African countries without patents on HIV/AIDS medicines, of which there are many, could legally import Cipla's medicines if subsidized through aid. However, both Cipla and Africa countries are reluctant to face costly litigation, even if frivolous, when threatened by the pharmaceutical industry.
- In February, 2001, the U.S. advanced a complaint against Brazil at the World Trade Organization over its production of generic AIDS drugs, which had decreased prices by nearly 72%. In what many had called a model solution to the AIDS crisis, Brazil has provided free AIDS drugs to over 90,000 citizens, and cut its infection rate and death toll in half since 1997. Although Brazil's program was temporarily endangered by the strong-armed tactics of big drug companies acting through their proxy, the U.S. Trade Representative, the U.S. withdrew its WTO complaint on June 25, 2001.
  - The technical legal basis of the complaint was quite narrow. The U.S. Trade Representative claimed that the Brazilian Act discriminated against imports because it permitted compulsory licensing where a patent holder did not work the patent by manufacturing domestically.
  - However, it is no accident that the complaint followed upon Brazil's offer to export its dramatically cheaper medicines to Africa and to transfer its technology and expertise.
- More recently, in March of 2001, Merck threatened to take Brazil's state-owned pharmaceutical manufacturer, Far-Manguinhos, to court for violating its patent on Strocrin by importing a generic form of the drug from India.
  - The threatened lawsuit was designed to stop Brazil from importing limited quantities of Strocrin, which Brazil is reverse-engineering so as to be able to produce a generic equivalent in the event

<sup>94</sup> Patrick Bond, *Globalization, Pharmaceutical Pricing and South African Health Policy: Managing Confrontation with U.S. firms and Politicians*, 29 Int'l J. of Health Services \* (1999).

- Merck does not agree to dramatically lower its prices.
- On March 30, 2001, Merck agreed to lower its Brazilian prices by nearly two-thirds. Although Brazil agreed to and praised the discount, it did not agree to stop its efforts to produce even cheaper generic equivalents.

### *Pfizer's Representative Role in the African Aids Pandemic*

Pfizer, Inc., based in New York City, and building new world research headquarters in New London, Connecticut, is the largest drug maker in the United States and now in the world.<sup>95</sup> Pfizer has a hugely profitable product line of blockbuster drugs: Lipitor, a cholesterol drug, Zoloft, an anti-depressant, and Viagra, the new male-impotency pill. Pfizer's rate of income growth is truly staggering; its 1999 revenue was estimated at \$16.2 billion, 284% more than the previous year. In 2000, following the acquisition of Warner-Lambert, its estimated revenue was \$31 billion. Not only is Pfizer huge, it is hugely profitable. Admittedly, the pharmaceutical industry in general is highly rewarding. In 1999, its ten largest members "earned" \$28.3 billion in profit and a rate of return on revenue of 18.3%. During that same time period, Pfizer/Warner-Lambert had total profits of \$4.912 billion on gross revenues of \$29.133 billion, a 16.8% rate of return.<sup>96</sup>

Of the 40 million persons currently living with HIV/AIDS, approximately 4 million will die of an opportunistic infection, cryptococcal meningitis, a fungal infection of the brain. Cryptococcal meningitis is excruciatingly painful and invariably fatal. When left untreated, after days of head-splitting pain, its victims lapse into a coma, dying within weeks of infection. Hundreds of thousands more will succumb to another fungal infection, esophageal candidiasis, which makes swallowing difficult and eventually impossible. An even larger number will suffer oral thrush, a childhood disease in the North, which creates painful mouth sores and difficulties eating and drinking.

Fluconazole is the best anti-fungal agent invented by modern bio-science. It treats women's yeast infections, toenail fungus, children's oral thrush, and, significantly for the HIV/AIDS pandemic, it is the only effective treatment for cryptococcal meningitis and is the treatment of choice for esophageal candidiasis. Although short-term fluconazole therapy is appropriate for esophageal candidiasis and oral thrush, once a patient starts taking fluconazole for cryptococcal meningitis, the patient will have to stay on the drug for life because of the danger of reoccurrence.

Pfizer patented fluconazole in 1982 under the trade name Diflucan. Pfizer sells roughly \$1 billion worth of fluconazole a year at wholesale prices that vary widely from \$3.60 a pill in Thailand, where it faces competition, to \$18.00 a pill in Kenya and over \$27.00 a pill in Guatemala, where it doesn't. The average wholesale price, worldwide, is around \$10.00 compared to \$12.20 in the U.S. Until recently, there were two prices in South Africa, \$4.10 and \$7.00 in the public and private sectors respectively. After retail markups, the drug sold for \$20.75 in South Africa's private pharmacies; thus, the two-pill maintenance dose for cryptococcal meningitis could cost as much as \$41.50 per day. In comparison, generic fluconazole is manufactured and sold for a profit much more cheaply in India, Bangladesh, and Thailand. How much more cheaply can high quality generic fluconazole be produced – 80% less? 90% less? In

<sup>95</sup> In June of 2000, the Federal Trade Commission approved the merger of Pfizer and Warner-Lambert, making Pfizer not only the world's largest pharmaceutical company but also the world's 5<sup>th</sup> largest company.

<sup>96</sup> Public Citizen's Prescription Drug Update – Drug Company Profits (October 11, 2000), at <http://lists.essential.org/pipermail/pharm-policy/2000-October/000407.html> (10/13/2000).

fact, fluconazole can be produced for 97-99% less – for as little as \$.24 per pill wholesale in Thailand, or more recently for \$.10 a pill in India.

Given the enormity of the AIDS pandemic and the impoverished conditions of sub-Saharan Africa, the obvious solution to the problem of opportunistic fungal infections would be to import cheap generic drugs or to manufacture generic fluconazole in Africa itself. Instead of spending thousands of dollars a year per patient, poor African countries could spend less than \$70 per patient per year. Such low prices would not only free up money to treat more patients, it would also encourage governments to invest in medical and public health infra-structure which many currently neglect partially because of unaffordability of medicines. But Pfizer would not let African countries import generic fluconazole nor would it voluntarily permit African countries to produce generic versions on their own. Instead, until World AIDS Day, December 1, 2000, Pfizer insisted on enforcing its patent so as to effectively embargo fluconazole from that area of the world where it was most needed.

### *What Does Pfizer (And The Drug Industry) Do With Its Money?*

The standard pitch from the pharmaceutical industry in general, and Pfizer in particular, is that it needs a high rate of return to compensate for the risks of researching and developing life-saving and life-enhancing medicines. During the 1990's, the industry claimed that it cost an average of \$500 million to research and develop major drugs and that it took eight long years to bring drugs to market; given a recent Tufts study, the industry will claim R&D costs of \$802 million per successful drug.<sup>97</sup> But is R&D a major component of price? Not unexpectedly, many consumer advocates question the industry figures, finding R&D costs to be much lower.<sup>98</sup> Even if there are significant R&D costs, these costs, subsidized by U.S. taxpayers, pale compared to astronomical marketing costs and profit margins. For example, 1997 IRS data on pharmaceutical research and development expenditures showed that R&D was only 7.4% of global sales (\$12.903 billion/\$175.3 billion).<sup>99</sup> Two years later, in 1999, the pharmaceutical industry spent three times more on marketing and administration than on research and development and earned 50% more on profits than it spent on R&D.<sup>100</sup> In 1999 alone, the industry spent \$13.7 billion on direct marketing costs, such as the now ubiquitous television ad, nearly 55% of its collective research and development budget.<sup>101</sup>

Pfizer, in particular, spends more than any other drug company to advertise to its consumers, both through direct marketing and through aggressive marketing to medical providers.<sup>102</sup> In 1999, the company spent 39% of its \$16.2 billion revenue on marketing and administrative costs; Warner-Lambert spent 46.1% of its \$12.929 billion. Between them, Pfizer and Warner-Lambert spent three times as much on marketing and administration as on research and development (\$12.310 billion vs. \$4.035 billion). Pfizer announced plans to spend about \$4.7 billion dollars on research in 2000, but 25% of that was on so-called Phase 4 studies, conducted after the FDA approves a drug and aimed at increasing sales by treating other related illnesses or by favorable comparison to competitors' drugs.<sup>103</sup>

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<sup>97</sup> BNA Daily Report for Executives No. 230, Monday December 3, 2001. Page A-8.

<http://lists.essential.org/pipermail/ip-health/2001-December/002490.html> (1/4/02).

<sup>98</sup> In June 2001, Public Citizen's study, *Rx R&D Myths*, estimated development costs at \$120 million per successful drug.

<sup>99</sup> <http://lists.essential.org/pipermail/pharm-policy/2000-June/000227.html> (08/17/2000).

<sup>100</sup> Public Citizen's Prescription Drug Update – Drug Company Profits (October 11, 2000), at <http://lists.essential.org/pipermail/pharm-policy/2000-October/000407.html> (10/13/2000).

<sup>101</sup> Merrill Goozner, *The Price Isn't Right*, 11 *The American Prospect* No. 20 (Sept. 11, 2000).

<sup>102</sup> Melody Petersen, *What's Black and White and Sells Medicine?*, *New York Times* (8/27/2000).

<sup>103</sup> *Id.*

Not only is research and development a relatively small part of the pharmaceutical dollar, the alleged \$500-\$800 million cost to create a new drug is greatly exaggerated. As early as 1993, it was pointed out that two-thirds of development costs of drugs arose during pre-clinical research, much of which is government funded.<sup>104</sup> This predominance of publicly funded basic research is particularly true for HIV/AIDS anti-retroviral medications virtually all of which were developed in the public and academic sector before being licensed to pharmaceuticals to sell at whatever inflated price they choose.<sup>105</sup> As another form of federal subsidy, the industry conveniently neglects to mention that the vast majority of its R&D costs are tax deductible, resulting in billions of dollars in tax write-offs. Moreover, FDA statistics for the 1990s suggest that about one half of industry research is directed toward me-too drugs, drugs that have therapeutic qualities similar to those of one or more already marketed drugs.<sup>106</sup> Sometimes these are “new” dosages, sometimes “new” combinations, and sometimes “new” delivery forms, i.e., capsules instead of pills. In each instance, the discovery value is minimal, but the monopoly extension rewards are immense.

Finally, industry’s claim that it is at the forefront of path-breaking biomedical research is greatly exaggerated. “A 1997 National Science Foundation study of biomedical patents found that only 17% of key discoveries came from industry. The vast majority were generated by public, not-for-profit, and foreign labs.”<sup>107</sup> Equally damning, 90% of pharmaceutical research is directed at First World diseases affecting only 10% of the world’s population; the endemic diseases of the South affecting 90% of the world’s people, i.e., malaria, tuberculosis, and now HIV/AIDS, receive only 10% of R&D investments.<sup>108</sup> Thus the “useful” path-breaking component of research and development is only a fraction of the amount sensationalized in the industry’s publicity and disinformation campaigns. So much for the preeminence of research and development and the R&D defense.

*Responding to a Public Relations Nightmare: Corporate Discount, Donation,  
and Patent Offers*

The multinational drug industry has faced a public relations nightmare. Because consumers have become increasingly aware of the industry’s price-gouging, both internally in the U.S. and internationally as well, and because the industry has been successfully and repeatedly targeted by U.S. and African AIDS activists, pharmaceutical companies have attempted to garner positive publicity by a series of price discount, drug donation, and patent relief programs. Although the number of corporate press releases has been large, the number of medicines actually received has been miniscule until very recently. Nonetheless, several initiatives are worth mentioning.

*1999 Bristol-Myers Squibb – Secure the Future*

The first highly touted corporate response to the African AIDS pandemic was launched by Bristol-Myers Squibb in the spring of 1999, its so-called Secure the Future program. With this program, the company promised \$100 million dollars over five years to fight AIDS in Africa. Despite promising to

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<sup>104</sup> *Id.*

<sup>105</sup> Consumer Project on Technology, *Additional Notes on Government Role in the Development of HIV/AIDS Drugs* (Feb. 23, 2000). <http://www.cptech.org/ip/health/aids/gov-role.html> (3/14/01).

<sup>106</sup> *Id.*

<sup>107</sup> *Id.*

<sup>108</sup> World Health Organization, *Macroeconomics and Health: Investing in Health for Economic Development*, 76-86 (Dec. 20, 2001) (arguing that 95/5 is a closer estimate); Medecins Sans Frontieres Access to Essential Medicines and the Drugs for Neglected Diseases Working Group, *Fatal Imbalance: The Crisis in Research and Development for Drugs for Neglected Diseases*, 10, (Sept. 2001).

benefit “millions of African women and children” (men need not apply), by the end of 2000, seventy-seven percent of the money had gone to U.S.-based charities and medical research institutions, including Harvard’s AIDS Institute.<sup>109</sup> Moreover, because Bristol-Myers had trouble imposing its vision on South Africa, it chose instead to focus its efforts on Botswana, a country with the world’s highest adult infection rate, nearly 40%, but with a relatively small population, approximately 1,6 million people. Although it is still far too early to judge the success of the many small projects that Secure the Future has funded, it is fair to say that the company did not have plans to supply large quantities of heavily discounted medicines through this initiative.

#### *2000 UNAIDS/Big Five – Accelerated Access Program*

The second major drug company initiative occurred on May 11, 2000, when, in conjunction with UNAIDS, a consortium of pharmaceutical giants, Bristol-Myers Squibb, Glaxo Wellcome, Merck, Boehringer Ingelheim, and F. Hoffman-La Roche, announced that they had committed in principle to substantial reductions of HIV/AIDS medicines in poor countries. Although the companies declined to commit to specific reductions, choosing instead to negotiate drug by drug, company by company, country by country, they did announce five broad conditions on their price reduction program: (1) “unequivocal and ongoing political commitment” by the recipient countries” to a comprehensive HIV/AIDS program; (2) agreement by international agencies, particularly WHO, UNAIDS, and the World Bank to assume responsibility for increasing public health infrastructures sufficient to monitor patient and their compliance with drug dosing regimes; (3) reduced cost drugs, would be sent only into “an efficient, reliable and secure distribution system” to prevent interruption of supply and treatment and to prevent theft and diversion of supplies into a gray market that would subvert existing first world markets and profit margins; (4) acknowledgement that “affordability is an issue in developing countries” and that there would be unspecified price reductions (subsequently estimated at 80-90%); and (5) that developing countries and international bodies would support “adequate and enforced intellectual property rights” to “provide a satisfactory return on investment in the high-risk search for new medicines.”<sup>110</sup>

In the first ten months, the Big Five succeeded in negotiating agreements for discounted medicines with only four countries, Senegal, Uganda, Ghana, and Ivory Coast, affecting only 2800 persons,<sup>111</sup> over the next ten months, only six other countries have been added.<sup>112</sup> Because of the slow pace of the “Accelerated” Access Initiative, the Big Five promised to country-by-country negotiations and to negotiate on regional, price-transparent basis. That promise, however, has never been fulfilled. Thus, the pharmaceutical cartel is reported to be in continuing negotiations with South Africa and other African countries, seeking limited price reductions to the public sector only that will preserve rights to charge high prices in the first world and to local elites,<sup>113</sup> while still managing, if possible, to make marginal profits on high-volume sales at reduced prices should donor funding ever materialize.

In response to growing threats of generic production, discussed below, the industry initiated a new round of press releases announcing unilateral price reductions, starting first with Merck, which on March 7, 2001 announced a further 43-55% discount off its leading protease inhibitors. Although initially touted as being universally available, subsequent news reports clarified that Merck’s price reductions would not apply to all African countries nor to all Latin and South American countries. Nonetheless, as Big Pharma

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<sup>109</sup> Bill Brubaker, *The Limits of \$100 Million: Epidemic’s Complexities Curb Impact of Bristol-Myers Initiative*, Washington Post (Dec. 29, 2000). (<http://www.washingtonpost.com/ac2/wp-dyn/A60114-2000Dec28?language=printer>) (1/02/2001).

<sup>110</sup> Barton Gellman, *A Turning Point That Left Millions Behind*, Washington Post (Dec. 28, 2000) (<http://www.washingtonpost.com/ac2/wp-dyn/A56492-2000Dec27?language=printer>) (1/02/2001).

<sup>111</sup> Under this “grand” scheme, in the first three countries, only 2800 persons (900 in Senegal, 1500 in Uganda, and a few hundred in Rwanda) stand to benefit in the first few years; the number to benefit in Ivory Coast has not yet been estimated.

<sup>112</sup> UNAIDS Press Release, *UN Efforts Broaden Availability of Anti-retrovirals: “Accelerating Access” Initiative Moving Forward; 72 Countries Worldwide Express Interest* (December 11, 2001). ([http://www.unaids.org/whatsnew/press/eng/pressarc01/Ouagadougou\\_111201.html](http://www.unaids.org/whatsnew/press/eng/pressarc01/Ouagadougou_111201.html)) (1/2/02).

<sup>113</sup> For example, 20% of South Africans, those in the private health care sector, receive 67% of the country’s gross expenditures on pharmaceuticals.

continues to feel risk from a newly emerging and expanding HIV/AIDS generic industry, it can be expected to continue to undercut prices and to impose other barriers to avoid loss of market control.

#### *2000-01 Pfizer – Fluconazole Donation Program*

In an equally dramatic publicity campaign, shortly in advance of the International AIDS Conference in Durban, South Africa, and several times thereafter, Pfizer proudly announced its planned partnership with the South African Ministry of Health to provide free fluconazole to patients suffering from HIV/AIDS. What Pfizer did not announce was that it initially limited the donation in several important respects: (1) the drug would be provided only for treatment of cryptococcal meningitis not oral thrush or life threatening esophageal candidiasis; (2) the drug would be provided only for patients certified to be unable to afford the medicine, thus preserving excessive profits in the private sector; (3) the donation was structured in many ways as a clinical trial with onerous reporting, training, and certification requirements; (4) the donation was time limited to 2 \_ years only (the remaining life of its patent in South Africa) and subject to reevaluation at that time, despite a life-time need for most patients; and (5) the donation was announced for South Africa only leaving the rest of the developing world to fend on its own.

The Treatment Action Campaign in South Africa (TAC), which had been at the forefront of the growing international movement demanding access to treatment for HIV-positive Africans, demanded that the pharmaceutical industry in general, and Pfizer in particular, greatly reduce their prices and/or that they permit importation or local production of low-cost generic equivalents. Not only did TAC sponsor a demonstration of 8,000 activists at the International AIDS Conference, it launched a Defiance Campaign whereby it “illegally” imported generic fluconazole from Thailand and submitted samples to the South African Medicines Control Council for approval. TAC threatened free distribution to cooperating doctors and a stepped-up campaign of importation should the government refuse to license the drug, which it eventually did, on a limited basis, to one hospital.

TAC and other activist organizations resisted Pfizer’s phantom and highly conditional offer of “free” medicines because it did not provide a long-term solution to the problem of reliable long-term access to affordable medicines. Because Pfizer’s offer was time limited, patients could abruptly be denied treatment at the end of the donation cycle. Equally problematic, medical providers might become accustomed to prescribing the name brand and continue to do so when the donation program ends. The most counter-productive aspect of the donation program, however, was that the developing world needs to develop its own pharmaceutical capacity, organized on an international and/or local scale, so that it can produce more of the medicines it needs without one-sided reliance on the profit-driven pharmaceutical cartel.

On World AIDS Day, Dec. 1, 2000, after months of tense negotiations, Pfizer and the South African Department of Health announced an agreement concerning free distribution of fluconazole for two years in the public sector.<sup>114</sup> Although the exact parameters of this agreement were not immediately known, subsequent reports confirmed that activists and public health advocates had succeeded in “convincing” Pfizer to broaden the number of opportunistic infections to be treated and that they secured promises concerning the sustainability of supply to existing patients after the donation program ended. Unfortunately, Pfizer did not actually begin delivering fluconazole until March of 2001; it has also declined to improve affordability in the private sector or to extend its offer to other countries. In response to continued, widespread demands, Pfizer announced on June 6, 2001, that it would expand its offer of free fluconazole to least developed countries. Despite this promise, Pfizer did not memorialize it “expanded” donation offer until December 1, 2001, World AIDS Day, and then to only six African countries.

#### *2000 Boehringer –Mother-to-Child-Transmission Nevirapine Donation*

Around the same time that Pfizer announced its planned fluconazole donation program, Boehringer Ingelheim, the patent holder for nevirapine, announced that it would donate its medicine for five years throughout Africa to prevent mother-to-child-transmission. Like Bristol-Myers, which focused

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<sup>114</sup> Pfizer estimated the value of the fluconazole donation program at \$50 million, presumably based on the wholesale price of the donated medicine, not the \$1-2 million dollar actual cost of production. In addition, it is quite likely that Pfizer will end up with significant tax advantages, exceeding the costs of the program, because of current charitable deduction rules.

its Secure the Future program on women and children, Boehringer discovered that responding to “innocent victims” was politically and morally expedient. Moreover, nevirapine had several advantages over the longer AZT protocols used in the West, both because it was easier to administer (one dose to the mother during labor and another dose to the infant shortly thereafter) and because the dosage was substantially cheaper. Therefore, TAC and other treatment activists actively supported governmental acceptance and implementation of the nevirapine program despite reservations about donations as a general strategy.

Surprisingly, despite widespread support in civil society, there was considerable delay in accepting this program in South Africa, delay that was partially attributable to on-going clinical trials in South Africa and to the fact that the medicine had not yet been registered with the Medicine Control Council for mother-to-child usage. In course of this delay, the government raised questions about the toxicity of nevirapine, about drug resistance, and about the capacity of the health care system to administer a nevirapine program. Finally, however, in January of 2001, as pressure from civil society increased, as TAC threatened a human rights lawsuit, and as the S.A. Human Rights Commission investigated the government’s procrastination, the Health Department announced a limited pilot project that would involve testing/counseling, free nevirapine therapy, and free formula to pregnant women at 18 major public health facilities in South Africa.

Although activists were gratified with Boehringer’s long-term offer, still not accepted by South Africa, and were pleased that the South African government was finally implementing a partial program, they were disappointed that the initial program would reach only 10% of 1.2 million pregnant women. When it became clear that the government had no intentions to plan a nationwide program and that it continued to prevent public health sector doctors from prescribing nevirapine, TAC, medical providers and the Children’s Rights Center filed suit in October 2001, which they won on December 14, 2001. Unfortunately, the government has announced its intention to appeal, delaying implementation of the court order for nearly a year. During this hiatus, nearly 200,000 HIV-positive mothers are at risk of passing preventable infections to nearly 36,000 infants.<sup>115</sup>

#### *2001 Bristol-Myers Squibb – Price Reduction and Patent Relief Program*

On March 14, 2001, Bristol-Myers Squibb offered to make two of its AIDS medicines, Videx (didanosine) and Zerit (stavudine) available “below cost” at \$1 dollar per day to sub-Saharan African countries. Although gratified by the reduction, activists are already disputing that these prices are truly below costs. For example, instead of production costs of \$.85 for a daily supply of Videx, activists claim they have a \$.22 per day offer from a generic manufacturer. Similarly, the \$.15 per day offer for Zerit contrasts with a \$.05 per day offer in Thailand. Because of the lack of transparency about actual marginal costs of production and about existing excess productive capacity, activists remain skeptical about the accuracy of Bristol-Myers’ “rock bottom” prices. Activists are also decrying the geographic limitation of the offer, to sub-Saharan Africa only, a limitation that ignores the emerging epidemic in other poor regions of the world particularly Central and South America and Southeast Asia.

In an equally dramatic gesture, on July 1, 2001, Bristol-Myers offered “emergency patent relief” to Aspen Pharmacare in South Africa whereby it agreed not to sue the generic manufacturer for the next five years for its production and sale of Zerit and Vidix in South Africa and in 47 other African countries where it did not have a patent. Although there were reservations about the legal effect of the promise not to sue and some belief among activists that a non-exclusive voluntary license would have been preferable, the offer has been considered to be useful because it takes advantage of capacity in Africa, it is not limited to any particular sector, and it permits export to no-patent countries.

These two medicines have been at the center of the abusive pricing controversy because both had been discovered and developed at university and government expense before being licensed to Bristol-Myers. Zerit, for example, had been discovered originally at the Karmanos Cancer Institute in 1966 with public money and then rediscovered in 1986 and patented for HIV treatment in 1990 by Yale University,

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<sup>115</sup> Out of approximately 1.2 million births a year in South Africa, it is estimated that 240,000 mothers are HIV positive. Approximately a third of HIV positive women are believed to pass the virus on to their babies during or after childbirth equaling 80,000 cases of transmission. This rate of vertical transmission can be reduced approximately in half with anti-retroviral therapy administered during the birthing process. However, because the current program will reach less than 10% of the pregnancies, approximately 36,000 cases of preventable vertical transmission will still go untreated.

working under an NIH grant. The Yale patent was then licensed exclusively to Bristol-Myers, which has paid Yale approximately \$120 million in royalty fees over the last six years. With governmental assistance, Bristol-Myers conducted key clinical trials resulting in product approval in June of 1994. Students and other activists at Yale recently started campaigning against this university/pharmaceutical complicity. It was only after key newspaper articles reporting this campus-based activist campaign that Yale and then Bristol-Myers relinquished their patent rights to Zerit.

In the same vein, it is important to note that Videx had also been discovered and developed at NIH expense and that the U.S. government holds the actual patent. As part of its licensing agreement, Bristol-Myers is supposed to maintain a reasonable relationship between pricing and the health and safety needs of the public. In the absence of such a relationship, the government retains the right to license d4T to other entities, including WHO, foreign governments, and sub-licensees. Unfortunately, there are indications from NIH that the government will not allow licensing to WHO or other nations through fear of creating disincentives to the development of medical discoveries.<sup>116</sup> This reluctance will have little effect in Africa, however, because there are no records of Videx having been patented anywhere in the continent.

In any event, Bristol-Myers' philanthropic offer must be assessed in light of the role of the public sector in discovering and even patenting these essential medicines. Its research and development-based claims about cost recovery pricing are patently absurd and it faced growing embarrassment for continuing to charge monopoly prices<sup>117</sup> and for insisting on strong patent protection for these two essential HIV anti-retrovirals.

#### *Abbott Laboratories Offers to Sell Norvir and Kaletra at No Profit*

On March 27, 2001, Abbott Laboratories announced that it would sell two anti-retroviral medications, Norvir and Kaletra, in Africa at prices that would cover costs of manufacture, distribution, and import tax only, resulting in a price of less than \$1000 per year for each medication. To implement its discount-pricing plan, Abbott hired a consulting firm, Axios International, to help distribute the medicines. Countries and medical providers seeking to buy the discounted medicines would have to prove that they could properly treat patients and that patients would be monitored for side effects. Once again, activists are skeptical that the quoted prices really do not provide some cost-recovery or profits margin for Abbott.<sup>118</sup>

#### *A Cipla Bombshell: The Emergence of Generic Competition*

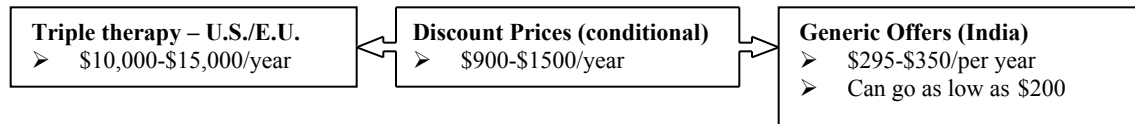
Because of delays and minimal impact in pharmaceutical initiatives, there has been an unprecedented amount of negative news and editorial coverage in major media sources, much of it outlining pricing/profit excesses in the pharmaceutical industry and pressing demands for additional price concessions and for aid from the developed countries for the purchase of lower cost medicines. In addition to this negative publicity, the industry was shocked by an offer in February, 2001 from Cipla, an Indian generic manufacturer, proposing to sell an annual package of triple-dose anti-retrovirals to Doctors Without Borders for \$350 per year and to sell those same medicines for only \$600 per year to African governments and NGOs doing AIDS work. Shortly thereafter, another Indian manufacturer, Hetero Drugs, offered the same medicines at a marginally better price of \$347.00 per year and has already negotiated a partnership with Aspen Pharmacare, the largest generics company in South Africa, to distribute its medicines. Even more recently, a third Indian generic manufacturer, Auribindo, has offered a triple dose therapy regime at \$295.00 per year. Not to be outdone, in the fall of 2001, Cipla has filed formal application for non-exclusive compulsory licenses to supply HIV/AIDS medicines to South Africa. The expectation is that competition between generic producers will continue to drive down prices,

<sup>116</sup> Melody Petersen & Donald G. McNeil Jr., *Maker Yielding Patent in Africa for AIDS Drug*, New York Times (March 15, 2001) <http://www.nytimes.com/2001/03/15/health/15AIDS.html?pagewanted=print>

<sup>117</sup> Medicins Sans Frontieres (MSF) estimated that BMS's profits on d4t between 1997 and 1999 were over US\$1 billion. In the first quarter of 1999, BMS made \$161 million from ddi.

<sup>118</sup> Melody Petersen, *Abbott to Sell Low-Cost AIDS Drugs in Africa* (March 18, 2001) <http://www.nytimes.com/2001/03/28/business/28DRUG.html>

such that the current lowest estimate for high volume, high quality triple-therapy generics is \$200 per year.



As a result of international activist pressure and low price offers from Indian generic producers, the pharmaceutical industry has launched a bewildering array of price reduction, donation, and patent relief programs during 2001.<sup>119</sup> The good news is that the cost of triple-therapy medicines, previously \$10,000-\$15,000 per patient per year, has been reduced by 85%-90% (primarily in the anemic public sector); the even better news is that the lowest price generics are now offered for two-thirds less. Accordingly, some previously price-embargoed drugs will reach a small number of Africans living with HIV/AIDS. The bad news is that the discount-pricing/donation programs are fractional, disjointed, provisional, and incoherent - offering some drugs, under special and limited conditions, to some countries for an uncertain period of time. However, the industry provides no comprehensive plan for widespread delivery of affordable life-saving medicines to both the private and public sector and even less planning for the development and enhanced distribution of the next generation of HIV/AIDS medicines. Moreover, the industry continues to erect and enforce barriers to the development of a sustainable generic industry. Thus, without a doubt, access problems still exist, what the industry has given it can take away.

*Pharmaceutical Companies' Interests and Objectives  
In Negotiating Donations and Price Reductions in Africa*

Based on announcements and initiatives from pharmaceutical giants, it is possible to analyze some of the underlying interests and objectives impacting their ongoing negotiations in Africa:

1. The vast majority of pharmaceutical sales and profits (80% of sales and over 80% of profits) is in the First World, mainly the United States and Europe, but also in Japan and other wealthier parts of Asia. The drug companies' primary interest is to protect their sales and high profit margins in these First World markets. Even though Africa accounts for only 1.3% of global pharmaceutical sales, inroads by cheap generics in Africa would threaten to bleed back into the First World either by: (1) direct comparative evidence of the low cost of manufacture and thus the exorbitant prices/profits of the major pharmaceuticals leading to demands for price reductions or price controls; and (2) the development of a gray market whereby cheap generics could be re-exported to First World markets.
2. Despite having relatively small markets in the developing world, pharmaceuticals do sell to local elites and managers/professionals in the formal economy. A few African countries have a relatively privileged private health sector that caters to the comparatively rich. Drug manufacturers are reluctant to lose these local profit centers through the provision of low-cost generic drugs in the public health sector. Even though only 30,000 or so Africans are receiving full anti-retroviral AIDS therapy, companies continue to make substantial profits on those sales.
3. Pharmaceutical companies have an interest in recouping their research and development costs in a highly competitive drug environment. Although drug R&D is highly tax subsidized, although much of it is public-sector financed to begin with, and although R&D costs are often exaggerated in industry statements, drug companies do invest a lot of money and time in developing major new pharmaceutical products. In addition, their investors, i.e., stockholders, have come to expect a very high rate of return.

<sup>119</sup> Carmen Perez-Casas et al., *Accessing ARVs: Untangling the Web of Price Reductions for Developing Countries* (Campaign for Access to Essential Medicines, MSF, October 5, 2001).

Moreover, a great product in year one can be superseded by a competitor's superior product in year two, turning a potential block-buster drug into a giant flop.

4. Drug companies have an interest in developing and maintaining brand loyalty. Although the vast majority of marketing expenditures is spent with medical professionals, companies are now advertising directly to consumers as well.
5. Drug companies are interested in maintaining their competitive edge in developing and patenting new pharmaceutical products. Not only are they interested in expanding patent rights with respect to existing products, e.g., patenting expanded usages, minor variations in dosage, and same company drug combinations, they are also interested maintaining access to academic and governmental research and development and expanding their own governmentally subsidized research and development capacity. Coming up with major new drugs, results in a 20-year monopoly during which it is possible to generate truly extraordinary profits.
6. The drug companies are interested in protecting their intellectual property rights, even in the developing world, to avoid competition from manufacturers of low-cost generic drugs. The drug companies espouse and promote extremely rigorous manufacturing standards in part as a barrier to entry by generic competitors. In addition to disparaging generic competitors, drug companies attempt to limit generic manufacturers' markets, particularly by limiting their capacity to export products to other countries – the larger the market, the more the economies of scale and the lower the eventual price. Thus, the major manufacturers attempt to prohibit regional generic cooperation in the South so that each country faces the prohibitive task of putting together its own pharmaceutical capacity. Though Brazil, India, and Thailand have been able to do so, and although certain Southern African countries might be able to do so, particularly South Africa, most small, poor African countries lack the technical expertise and manufacturing capacity to manufacture a broad spectrum of pharmaceutical products even from imported ingredients.
7. The drug companies depend on the goodwill of developing companies for their clinical trials. Thus, they have some interest in providing drugs under controlled conditions if that leads to governmental goodwill and collaboration with local medical personnel.
8. The drug companies are extremely dependent on positive publicity because their excessive profitability and the increasing unaffordability of medicines, even in the First World, renders them vulnerable to public and governmental opinion (and this affects stock values). Accordingly, drug companies have attempted to gain credibility by tightly structured and time limited donations and/or reduced cost programs.
9. With respect to these programs, the drug companies like to be in control and to negotiate drug by drug, country by country. They resist negotiating with a coalition of developing countries just like employers have historically resisted negotiating with unions. They fear that a unified opposition will negotiate on stronger terms. Of course, variations in local conditions and local markets also make country specific negotiations rational to some extent.
10. Despite painting pharmaceuticals with a broad brush, there are tactical differences within the industry. Moreover, there appear to be altruistic people within the industry who are sincerely interested in increasing access to affordable medicines.
11. Pharmaceuticals are fearful of the possibility of divestment and corporate responsibility campaigns that keep them in the news and that threaten the confidence of their stockholders. The past history of divestment campaigns in support of South Africa would resonant strongly with a new divestment campaign aimed at pharmaceutical AIDS profiteering. Bristol-Myers Squibb capitulated quickly on its anti-retrovirals in part because of the complicity campaign started at Yale.

12. Pharmaceuticals are interested in so over-stepping their political protection that there is pressure to impose price controls, disclosure rules, and other provisions that expose them to more scrutiny and control.
13. In the long run, the industry hopes to crush or absorb the generic industry, particularly in India, that keeps snapping at its heels. As TRIPS becomes obligatory even in least developed countries and as the next generation of HIV/AIDS medicines are fully protected by patents against generic duplication, the generic industry will face significant threats to sustainability. Although it will always be able to produce end of patent generics, these older drugs are almost always supplanted by a superior line of new patented products that become the current standard of care. Even those generic manufacturers that survive will find themselves tempted by buy-out and acquisition offers. The new multinational owners can then either close the shop down or redirect its energies away from direct competition for current pharmaceutical products.

### CONTEXTUALIZING THE PANDEMIC: ANEMIC FUNDING

Even with discounted or generic prices, African countries and peoples will find it impossible to buy significant quantities of live-saving AIDS medicines.<sup>120</sup> Current budgets for public health in most sub-Saharan countries are woefully inadequate, on average \$13 per year per person.<sup>121</sup> Thus, a second prong of the access to treatment campaign (beyond dramatic price reductions for essential AIDS medicines) has focused on bilateral and multilateral funding of AIDS treatment on a massive scale. The history of funding for AIDS treatment in Africa has been shameful. During most of the 1990's the actual per person expenditure on all AIDS prevention and treatment programs in Africa dropped to as little as \$3 per person per year.<sup>122</sup> Although the U.S. champions its status as the nation providing the most support for international AIDS programs, its bilateral funding through USAID, CDC, and other federal agencies has been painfully inadequate.<sup>123</sup>

In response to the inadequacy of donor funding, on April 28, 2001, Kofi Annan, General Secretary of the United Nations, called for the establishment of a Global Fund dedicated to the fight against HIV/AIDS, tuberculosis, and malaria. Drawing on existing social science research, Annan estimated that an initial response to AIDS, TB, and malaria in low- and middle-income countries would cost between \$7 and \$10 billion dollars a year, with half of those resources needed in sub-Saharan Africa. These funding needs would expand over time; thus, a UNAIDS report published in *Science Magazine* on June 22, 2001, estimated that the world's poorest 135 countries would require \$3.2 billion dollars in 2002 and \$9.2 billion dollars by 2005 for a comprehensive AIDS prevention, treatment, and care program alone. Of the \$9.2 billion, \$4.8 billion would be spent on prevention efforts and \$4.4 billion on treatment, including \$1.13 billion for the purchase and distribution of anti-retroviral medicines at rock-bottom prices. Expenditures

<sup>120</sup> Markus Haacker, *Providing Health Care to HIV Patients in Southern Africa*, IMF Policy Discussion Paper No. 01/3 (October 2001) (concluding that only South Africa and Botswana have even limited capacity to provide significant access to lowest cost medicines).

<sup>121</sup> In the world's 60 poorest countries, including most of sub-Saharan Africa, an average of \$13 is spent per person per year on health care. This compares to \$2000 per year in developed countries and \$4500 per year in the U.S. The richest countries in Southern Africa, Botswana and South Africa spend the equivalent of \$398 and \$552 respectively on health care expenditures. *Id.* at 4.

<sup>122</sup> Attaran & Sachs, *supra* note \*.

<sup>123</sup> The fiscal year 2001 budget for international HIV/AIDS is approximately \$460 million, which doubled the budget the year before. Of this amount, \$260 million only went to fighting HIV/AIDS in Africa. The Senate, on April 5, 2001, passed a budget proposal that would boost the fiscal year 2002 funding to \$660 million and the fiscal year 2003 budget to nearly \$1.1 billion, the "bulk" of which would go to countries in sub-Saharan Africa. These figures fall far short of the figures necessary to support an effective program.

for treatment would expand over time as health care delivery capacity increased and as more people living with HIV reached the clinical threshold for ARV therapy.<sup>124</sup>

Despite great fanfare, initial funding for the Global Fund, now named the Global Fund to Fight AIDS, TB, and Malaria, has been disappointing at best. The U.S. set the bar extremely low by offering only \$200 million dollars, less than 10% of what it should have offered as the world's largest economy.<sup>125</sup> This paltry sum was eagerly matched with low-ball offers from former European colonial powers. The net effect, after all the press releases, is that the multi-billion Global Fund is currently funded at \$1.6 billion as of December 2001, only \$700 million of which is available for spending in the year 2002. Given that these funds must be spread among prevention, treatment, care, and capacity building for all three diseases, there a serious question whether the level of funding is designed for success - or for failure. By being the first government to announce a donation and by setting the bar so low, the Bush administration has threatened to asphyxiate the Fund before it starts. In the final analysis, the U.S. seems to be engaged in the cynical game of trying to calculate the minimal amount of funding that will permit it to argue that it "responded" to the pandemic and then to withdraw that funding once the under-funded campaign inevitably fails.

In addition to this gross under-funding, the administration has also subverted the promise of the Fund by steering it almost exclusively toward failed prevention policies, including the politically expedient abstinence message, by opposing bulk purchases of medicines and medical supplies, and by securing corporate "participation" within the governance structure. It also lobbied strongly that Fund moneys be used only to purchase patented medicines rather than the

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<sup>124</sup> Other researchers have proposed similar levels of funding, e.g., Individual Members of the Faculty of Harvard University, *Consensus Statement on Anti-retroviral Treatment for AIDS in Poor Countries* [http://www.hsph.harvard.edu/organizations/hai/overview/news\\_events/events/consensus\\_aids\\_therapy.pdf](http://www.hsph.harvard.edu/organizations/hai/overview/news_events/events/consensus_aids_therapy.pdf) (4/10/01). In the *Consensus Statement*, 128 Harvard faculty members endorsed a proposal for fighting AIDS in sub-Saharan Africa that would cost \$4.1 billion a year during the first three years and then expanding the program to \$6.3 billion in 2005 as more African receive anti-viral therapy. The proposal requests that the U.S. government's initial funding would be \$1.5 billion a year. The funding would predominantly be used for prevention and non-anti-viral treatments (75%) during the first three years, while one million Southern Africans would receive anti-viral therapy costing \$650 a year plus another \$483 a year for testing and monitoring. The funding proposal does not directly discuss money for building medical infrastructure and for medical training. Instead, it discusses using a form of directly observed therapy, such as that used in treating drug resistant tuberculosis.

Critics of the Harvard proposal question whether the money demands are high enough and whether the time-line is proactive enough. In addition, it has become clear that the Harvard group foresees purchases from the patent drug industry instead of licensing and cheaper production by generic manufacturers. Thus, it seems to preclude alternative sources of supply that might be much cheaper than \$650 a year (lowest estimate from generic manufacturers at sufficient economies of scale is \$200 a year).

In its recent Report, *Macroeconomic and Health: Investing in Health for Economic Development* (Dec. 2001), the World Health Organization proposed dramatically increased expenditures in health for the world's poor over time. It found that the current level of official development assistance for health stands at about \$6 billion per year. The Report recommended that this spending should be increased to \$27 billion by year 2007 and \$38 billion by 2015; these figures will be supplemented by increased expenditures from developing countries as well. The goal is to provide funding equaling at \$38 per person by year 2015 which would allow nations to provide essential health interventions including treatment for malaria, tuberculosis, AIDS, and childhood infections as well as immunizations, prenatal care and other prevention services. The Report estimates that there would be direct and indirect benefit of nearly \$360 billion per year by 2015-2020 from increased health investment of \$66 billion per year above current spending. With respect to the Global Fund, the Report endorses a scaling up to \$8 billion by 2007 and significant expenditures on HIV/AIDS prevention, treatment and care in developing and impacted countries (\$6 billion, \$5 billion, and \$3 billion respectively by 2007).

<sup>125</sup> Based on its GNP, the U.S. commitment should have been in the range of \$2.5 billion in the first year.

much cheaper generic equivalents that can be sold without violating patents in the many African countries that do not yet have patents on HIV/AIDS medicines and in the countries that might legally authorize compulsory licenses for these life-extending anti-retroviral medicines. This position by the U.S. provoked heated opposition by its European partners who did not relish subsidizing the U.S. pharmaceutical industry and by a coalition of developing countries and treatment activists. After a series of negotiations on the structure and operating principles for the Fund by the so-called Transitional Working Group, the U.S. finally backed down on its over-emphasis on prevention, its opposition to bulk procurement, and its opposition to purchase of generic production (so long as intellectual property rights are protected).<sup>126</sup>

Admittedly, multi-lateral funding through the Global Fund is not the only available source of funding for the pandemic. A significant portion of U.S. expenditures is made bilaterally through USAID (normally for procurement of U.S. products). Likewise, the G-7 is considering a \$1 billion trust fund for research into multiple tropical diseases.<sup>127</sup> Similarly, private philanthropists and foundations are also increasing their support, i.e. Bill Gates has promised to raise \$375 million for AIDS vaccine research. Even when these figures are totaled, however, they are grossly inadequate compared to the immediate need of \$7-10 billion per year.

#### LEGAL AND NON-LEGAL FACTORS AFFECTING ACCESS TO HIV/AIDS MEDICINES

Despite historically excessive prices and grossly inadequate funding, access barriers to medicines are not simply financial. The pharmaceutical industry still wields tremendous power and has various forms of legal and non-legal leverage that strengthen its monopoly position; moreover, there are multiple institutional and pragmatic barriers on the ground that forestall widespread distribution of affordable HIV/AIDS medicines. Thus, it is important to examine these barriers that complicate access to medicine before examining in more detail the international intellectual property framework that enables and constrains governmental, legal, and popular activism designed to secure access to affordable medicines. Because of the innumerable variables that can arise in any such analysis, I will concentrate primarily on the situation in South Africa.

One way of mapping the legal, medical, and institutional factors that impact the accessibility of HIV/AIDS medicines in Africa is to trace the progression of a medicine from the discovery to the delivery phase. At the same time, one can explore non-wholesale-price barriers that are particular to HIV/AIDS medicines. This tracing is not meant to be exhaustive but rather suggestive of the complications that impede access to patented HIV/AIDS medicines and to effective treatment with those medicines for Africans living with HIV/AIDS.

#### *Introduction to the National Patent and Drug Registration Regime*

In the classic, "pre-TRIPS" era, patent law was essentially national. Each sovereign nation passed patent legislation designed to suit its own internal interests taking into account its stage of development, appropriate rewards for inventors/investors, and lower costs and increased availability for consumers and derivative users of intellectual property. During this classic era, countries could discriminate between fields of discovery and exclude patents for medicines, e.g., Brazil; they could decide to patent pharmaceutical processes but not pharmaceutical products, e.g., India; or they could decide to limit the duration or scope of medical patents. Accordingly,

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<sup>126</sup> 121 U.S. Comments on Draft Proposal "Quick Start" (December 10, 2001).

<sup>127</sup> 122 Michael M. Phillips & Yaroslav Trofimov, *G-7 Nations Ponder Footing Bill to Fight AIDS in Poorer Countries*, Wall Street Journal (March 13, 2001) <http://www.aegis.com/channel/s/WJ010310.html>

for example, prior to TRIPS, about 50 countries did not grant any patent protection whatsoever for pharmaceutical products, including both developed and undeveloped countries.<sup>128</sup>

Operating in this classic system, an inventor of a pharmaceutical product/process would ordinarily have to file relatively contemporaneous patent applications in each sovereign state in order to protect its intellectual property rights in each country. A product or process could not be patented in South Africa merely because a patent application had been filed in the U.S. Moreover, in filing a separate patent application in South Africa, the patent seeker would be bound to the local patent law of South Africa both procedurally and substantively. Thus, a poor country that wanted to make sure that it would have access to low cost generic medicines could have, and often did, exclude patents for pharmaceutical products.

*Even Though ARVs are not Widely Patented in Africa, Patents Matter*

At this point, it is important to acknowledge that HIV medicines have not been patented pervasively throughout the developing world, particularly in sub-Saharan Africa, even in countries that have pharmaceutical patent regimes.<sup>129</sup> The explanation for this pattern of non-uniform patenting is that smaller and poorer nations do not have sufficient market size to warrant the cost of patent applications. Despite incomplete patenting, however, there are multiple anti-retroviral patents in those few countries - South Africa, Kenya, and Nigeria - that have meaningful market size and some pharmaceutical capacity. Similarly, there is a pattern whereby some of the most important low-dose, low-cost anti-retroviral medicines are patented in countries where the disease is concentrated.<sup>130</sup>

Unfortunately, some of the analysts who have reported the incomplete pattern of ARV patenting in Africa have reached the erroneous conclusion that "It is doubtful that patents are to blame for the lack of access to anti-retroviral drug treatment in most African countries."<sup>131</sup> This stunningly broad assertion rests on two observations: (1) the number of anti-retrovirals in use in Africa does not "correlate" with patent status of ARVs in particular countries and (2) actual use of drugs from a particular company does not seem to depend on patent status in Africa. The only reason that Attaran and Gillespie-White "get away" with their assertion is that they disaggregate price from patents and from the pervasiveness of patents in rich markets, as if monopoly prices are not connected to having secure patents in lucrative and rich markets throughout the world. While they do acknowledge that the overall poverty of African countries means that no country can currently afford anti-retroviral medicines without substantial international aid, they neglect to analyze that prices in Africa have remained high because of the absence of generic competition. Similarly, they have disregarded the increasing utilization of ARVs by rich and public sector elites in Africa as the prices of ARVs have dropped because of price discounts forced by treatment activists and by the mere threat of generic competition from Cipla and others. In fact, they assert, with no proof or analysis whatsoever, that "This scarcity [of treatment, 25,000 only]

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<sup>128</sup> Karin Timmermans and Togi Hutadjulu, *Report of an ASEAN Workshop on the TRIPs Agreement and its Impact on Pharmaceuticals* 11 (WHO 2000) (hereinafter, ASEAN Report). In fact, pharmaceutical patents were not uniformly recognized in the developed world until late in the 20th century: UK (1949), France (1960), Germany (1968), Italy (1978), Japan (1976), Sweden (1978), Switzerland (1977), and Spain (1992). *Id.* at 18.

<sup>129</sup> International Intellectual Property Institute, *Patent Protection and Access to HIV/AIDS Pharmaceuticals in Sub-Saharan Africa*, 47-51 (2000). Amir Attaran & Lee Gillespie-White, *Do Patents for Anti-retroviral Drugs Constrain Access to AIDS Treatment in Africa?*, 286 JAMA 1886, 1888 (Oct. 17, 2001).

<sup>130</sup> Low-cost, front-line anti-retroviral therapies involving 3TC, d4T, AZT, Abacavir, and/or Nevirapine are significantly blocked by patents in countries containing 68% of HIV positive persons in sub-Saharan Africa. Consumer Project on Technology et als., *Comment on Attaran/Gillespie-White and PhRMA Surveys of Patents on Anti-retroviral drugs in Africa* (Oct. 16, 2001).

<sup>131</sup> Attaran & Gillespie-White, *supra* note \*, at 1890.

cannot rationally be ascribed to anti-retroviral patents that are few - or nonexistent in most African countries."

Of course, a "rational" argument about the impact of patents does exist. If patent monopolies permit patent-holders to charge exorbitant prices (they do), if patent holders patent their products in all countries with any significant pharmaceutical purchasing or manufacturing capacity (they do and will do so even more in the future as TRIPS becomes mandatory in 2005/2006), and if patent holders can establish broader hegemony in worldwide markets through the threats of trade representatives and bilateral and regional treaties (they do), then patents affect affordability and thus access to medicines even in African countries where particular HIV/AIDS medicines are not patented. Just because patent holders achieve their twin objectives of market domination and control of U.S. trade policy other than through filing patent applications in every nook and cranny of the world does not mean that patents don't matter. For example, some African countries allow for exclusive registration of drugs patented elsewhere, many African countries' drug procurement systems, public and private, are habituated to dealing with major brands, and most countries are intimidated from negotiating with generic exporters or afraid of generic quality because of relentless Big Pharma propaganda about generics (even the highest quality ones). As a result of these patents and patent-related practices, patent holders can sell small quantities of branded medicines to African elites at a very high price with a very high profit margin at the same time that they have essentially marginalized the generic industry by a pattern of patenting that excludes the generic industry from any and all First World markets and from lucrative Southern markets like South Africa. Absent access to any markets with real purchasing power, generic companies will simply avoid the risk of economic failure

Unfortunately, patents not only impact price, they also impact the delivery of medicines in single-drug form versus in combination. The logic of the patent system is that patent-holders of different medicines will not combine them with medicines produced by a competing manufacturer. Since ease-of-dosing compliance is particularly important in resource strapped countries, it would be far better for patients to take triple-therapy combination medicines such as those being offered by CIPLA, than to take three times as many pills offered by brand name countries. These non-price effects of patents also matter.<sup>132</sup>

### *Barriers Arising from the Patent and Drug Registration Regime*

**Ownership of discovery.** The patent system rewards certain forms of human creativity that result in the invention/discovery of a novel industrial product or process. Yet, even this first step of inventive discovery is subject to independent ownership/ property/contractual relationships. Thus, for example, most universities now have rules and regulations governing the "ownership" of discoveries made by university employees. Similarly, corporate and governmental employers have private agreements and public laws regulating the ownership of discoveries made by their agents. More recently, research hospitals are selling first claims to medical discoveries to pharmaceutical partners who thereafter decide whether to pursue patenting and/or licensing rights.<sup>133</sup> To encourage transfer of discovery from the public to the private sector and to expedite its commercial exploitation, Congress has passed legislation, starting with the Bayh-Dole Act in 1980, designed to streamline such transfer.<sup>134</sup> Thus, the image of a solo

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<sup>132</sup> Brook K. Baker, *The Importance of Combo-Drugs: Another Argument for Compulsory and Voluntary Licenses* (e-mail August 10, 2001)

<http://lists.essential.org/pipermail/pharm-policy/2001-August/001352.html> (August 10, 2001).

<sup>133</sup> Liz Kowalczyk, *Beth Israel seeks deal with drug company*, Boston Globe (2/14/2001).

<sup>134</sup> See, e.g., Rebecca S. Eisenberg, *Symposium on Regulating Medical Innovation: Public Research and Private Development: Patents and Technology Transfer in Government-Sponsored Research*, 82 Va. L. Rev. 1663 (1996).

researcher discovering, owning, and exploiting a discovery based on his or her own creative genius and individual sweat equity is a quaint but obsolete ideal.

**Patentability.** The standards for patentability are novelty, an inventive step, and industrial applicability. Each of these is a contestable and ambiguous requirement and thus the legal gloss given to each can be highly significant in the pharmaceutical field. It is easiest to understand that new chemical entities might be patented, but what about processes such as gene sequences, or formulations such as capsules vs. tablets, or drug combinations, or new uses/second indications, or polymorphs of the same chemical? To the extent that a patent office applies loose standards of novelty, invention, or industrial application, it creates enormous barriers down the line for generic manufacturers and other competitors who are loath to incur the substantial costs of challenging a previously granted patent.

**Bio-piracy.** Likewise, it is important to consider the appropriateness of patenting the biomedical properties of plants that have been discovered by traditional healers and indigenous communities. This expropriation or bio-medical piracy of traditional medical discoveries without compensation to the originating communities is an increasing problem in the pharmaceutical field. It is estimated that if a 2% royalty were imposed on genetic resources discovered in the South, that the North would owe more than \$5 billion in royalties for medicinal plants alone.<sup>135</sup>

**Commercial feasibility.** The ability to make a profit drives almost all pharmaceutical research and development at this time. For example, the Orphan Drug Program in the U.S. grew out of the realization that there were costly life-saving medicines for some rare diseases but that it was not commercially feasible to test, develop, and market those drugs for a small market that could not afford to pay tens or hundreds of thousand of dollars. Likewise, this profit motive drives and orients pharmaceutical research towards consumers who can pay, through insurance or otherwise, and away from poor consumers who can't. Thus, 90% of the research and development budget for pharmaceuticals goes towards lifestyle disease of the North, e.g., high cholesterol, overweight, hair loss, and depression, affecting only 10% of the world's population. The remaining 10% of the drug research and development budget goes towards tropical and poverty-related diseases of the South affecting 90% of the world population, e.g., diarrheal diseases, respiratory diseases, tuberculosis, malaria, and now HIV/AIDS. Even in the context of AIDS, 95% of the AIDS vaccine trials currently in the pipeline are oriented towards the strain of HIV prevalent in Europe and the U.S., subtype A, instead of subtype C, a much more virulent form of HIV, that causes 90% of the infections in Africa and 75% of infections worldwide.<sup>136</sup>

**Filing a patent application.** Patent rights are based on the principle first in time, first in right, thus there is a premium on the rush to the patent office. The administrative ease of filing a patent application can therefore affect patent rights, though this seems to be a relatively minor impediment in the medicines arena. The patent application, however, must have sufficient disclosure of the discovery to permit replication by others at the end of the patent term. To the extent that this requirement is not scrupulously enforced, there will be barriers to the future production of generic medicines.

**Institutional incompetence in a patent office.** In order for the patent regime to work as designed, there should be a proper trade off between the public's interest in true innovation and the inventor's interest in a temporary monopoly. If a patent office is inefficient or error-prone in granting patents, it can either delay introduction of important discoveries or create false rights in non-novel inventions. In African countries, patent offices are so under-resourced and technically challenged that little meaningful review takes place. Sometimes it is hard to even get information about medical patents on file. Similarly, critics of the U.S. patent examination regime believe that a large percentage of patents "are not valid under any reasonable tests of utility and

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<sup>135</sup> OXFAM, *supra* note \*, at 32-33.

<sup>136</sup> Kaiser Daily HIV/AIDS Report, *AIDS Vaccine Development Not Targeting Common African HIV Strain, Harvard Expert Says*, (March 14, 2001).

invention.”<sup>137</sup> The improper granting of such patents creates substantial barriers to competing generic production of non-unique medicines, especially where national markets are small and where litigation costs are excessive, as they nearly always are.

**Registration.** In the medical field, there is an addition step that requires registration of a pharmacological product and approval of that product for designated medical purposes. In the U.S., this function is served by the Food and Drug Administration, which has relatively stringent, but not perfect, product-testing and safety standards. Many other countries have equivalent bodies; in South Africa it is the Medicines Control Council. As with the patent office, there are issues of institutional competence in medicine registration offices, some of which lack independent ability to monitor product safety. Many of these institutionally challenged offices rely on regional or foreign authorities to review the safety, efficacy, and quality of drugs destined for their markets. A 1993 WHO study found that only 3 of 36 African countries had even limited drug regulatory capacity; none had a comprehensive regulatory capacity.<sup>138</sup>

**Exclusive registration.** Some drug registration regimes allow “exclusive” registration of a product which in effect prevents parallel importation of the same medicine from another country where the patent holder or its authorized licensee has already exhausted its patent rights by a first sale. At a recent National Drug Policies course in Beirut, all of the countries attending except Kosovo reported having granted exclusive registration to the original patent holder, which gives the company super-monopoly status.<sup>139</sup> Similarly, in the U.S., registration of a pharmaceutical product triggers an automatic period of product exclusivity under FDA rules. Thus, even if the patent is ultimately proven to have been improperly granted, the patent holder gets a period of exclusivity.

**Pre-clinical and clinical trials.** As mentioned above, testing requirements for medical safety, efficacy, and quality are normally overseen by a registration office like the FDA in the U.S. These pre-clinical and clinical trials are a time-consuming and expensive and create major barriers to product development and ultimately to competition. The costs of trials are often partially borne by government grants, which was certainly true for the first generation of AIDS medicines. Recently, major questions have been raised about the frequent subcontracting of clinical trials and the practice of conducting those trials in developing countries where costs are cheaper, consent is easier to obtain, and safety oversight is lacking. Certain manufacturers, including Pfizer and Glaxo, have been at the center of recent scandals about irregularities and deaths in clinical trials in Africa. Moreover, there is a larger ethical critique when researchers stop treating patients at the end of trials and when the resulting medicines are unaffordable in the country where testing was conducted.

**Early working and stockpiling.** As a patent approaches its expiration date, it is useful for generic manufacturers to begin researching and testing the patented medicine so that they can start generic production as soon as the patent ends. There is also an advantage, if permitted, for the generic producer to begin stockpiling medicines for immediate post-patent sale. The so-called Bolar-exception in the U.S. permits early working that enables generic producers to start producing test batches of medicines in order to collect necessary data to submit to registration

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<sup>137</sup> James Love, *Access to Medicine and the Use of Patents without the Permission of the Patent Owner: Models for State Practice in Developing Countries*, 4 (draft Jan. 21, 2001)

<http://www.cptech.org/ip/health/cl/recommendstatepractice.html>

<sup>138</sup> World Health Organization, *Status of Drug Regulation and Drug Quality Assurance in WHO African Region and Selected Countries* (March 1999).

<sup>139</sup> Richard Laing, email (Nov. 20, 2000) <http://www.essential.org/pipermail/pharm-policy/2000-November/000491.html>

authorities. A recent WTO case from Canada also permitted this practice, although it outlawed stockpiling.<sup>140</sup>

**Legal restrictions on access to clinical test data.** In satisfying regulators about the safety, efficacy, and quality of a patented medicine, the patent owner frequently expends considerable time and expense in pre-clinical and clinical trials for new chemical substances, which it must thereafter submit to the registration authority. This information is ordinarily treated as a trade secret, which is protected against unfair competition. For example, TRIPS has a provision that provides conditional protection of confidential test data developed with considerable effort.<sup>141</sup> Some countries go even further and create “exclusivity” in test data, which means that this information cannot be used by another entity even pursuant to a compulsory license. If this TRIPS-plus concept of exclusivity is adopted, then a generic manufacturer with a compulsory license would have to repeat clinical tests at great cost. This cost burden creates significant barriers to entry.<sup>142</sup>

**Bio-equivalence.** One way that nations can get around the problem of data exclusivity is to accept proof of bio-equivalence in a second or subsequent registration of the same medical compound. The bio-equivalence standard avoids the economic waste of duplicative testing while still satisfying concerns that the drug is safe, efficacious, and high quality. The typical range for bio-equivalence is 90%-110% of the active ingredient.

**Patent extensions.** Patent regimes frequently allow the patent period to be extended because of regulatory delays in the marketing of new pharmaceutical products. It is true that the actual effective period of patent protection for new medicines is often less than the full 20 years because of long delays in obtaining marketing approval from public health regulatory bodies like the FDA, but these delays have been reduced by half in the last decade. Nonetheless, patent law in developed countries continues to permit patent holders to apply for patent extensions that can add years to a patent’s life. These extensions ultimately keep pharmaceutical prices and profits high as competition is delayed. In addition, at least in the U.S., a patent holder can get an automatic patent extension by conducting pediatric trials, a provision that is being increasingly abused.<sup>143</sup>

**Market domination and concentration.** Market domination and concentration, leading to an overall lack of competition, creates additional distortions in pricing in three circumstances. The first circumstance is when a truly innovative therapeutic agent faces little or no competition for a particular medical condition. Although competitors may begin to develop competing products after a break-through discovery, significant delays in discovery, registration, and testing can create near perfect monopoly conditions in the interim. Thus, the patent holder can charge as much as the market will bear. The second circumstance increasing pricing pressure is escalating market concentration resulting from a decade of acquisitions and mergers that has reduced effective competition in the pharmaceutical industry,<sup>144</sup> especially when the resulting mega-firms have rationalized their product lines to reduce the array of competing products. Of course, the Federal Trade Commission sometimes imposes conditions on anti-competitive mergers and requires sale or licensing of internally competing products to a competitor. Although this anti-trust solution has some utility in the short-run, in the long run, the number of competitors is reduced creating upward pressures on pharmaceutical pricing. The third circumstance again has

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<sup>140</sup> *Canada—Patent Protection of Pharmaceutical Products*, Report of the Panel, WT/DS114/R, March 17, 2000 [hereinafter *Generic Medicines*].

<sup>141</sup> Article 39.

<sup>142</sup> ASEAN Report, *supra* note \*, at 37-39.

<sup>143</sup> Rachel Zimmerman, *Drug Makers Find a Windfall: Testing Adult Drugs on Kids*, Wall Street Journal (Feb. 5, 2001).

<sup>144</sup> The industry has been marked by a wave of mergers and acquisitions in the 1990’s, culminating in two mega-mergers in the year 2000 that blended Warner-Lambert into Pfizer and that joined SmithKline Beecham to Glaxo Wellcome.

anti-trust implications and occurs when pharmaceutical companies act to reduce competition by buying start-up competitors and paying generic producers not to introduce competing products.<sup>145</sup> For example, on October 11, 2000, after two blatant examples of anti-competitive bribes to generic manufacturers, the Federal Trade Commission announced plans to subpoena records from 90 pharmaceutical companies to see how widespread the generic suppression practice was.<sup>146</sup>

### *Non-Patent/Registration Barriers to Access*

**Economies of scale.** One of the great conundrums in the access-to-medicines campaign is the issue of economies of scale. As discussed further below, there is some self-interest in the developing world to produce medicines locally when there is any industrial capacity to do so. On the other hand, there are cogent arguments that price reductions will be greatest when there are economies of scale, which suggests concentrating manufacture either in the existing pharmaceutical sector or, more plausibly, in the emerging generic sector. The problem with economies-of-scale analysis is that it directly contradicts the monopoly-pricing analysis that recommends competition to drive prices down. In the long run, however, it is likely that economies of scale will be critical to affordability and thus policy should be oriented towards supporting large-scale, price restricted production rather than encouraging competition between multiple small and inefficient manufacturers.

**Price controls (and their absence) and bulk purchases.** Although price control mechanisms are an anathema to free-market philosophy, there are no good reasons why pharmaceuticals with monopoly power should be entirely free to set their prices. Price control mechanisms have been used successfully in Europe, particularly in France and Spain. Similarly, Australia has experimented successfully with a price control mechanism that allows a commission to review the reasonableness of the industry's pricing practices. Another, more tradition means of moderating prices is to consolidate buying power for consumers. Thus, negotiation of bulk purchases can dramatically decrease wholesale prices. Although government programs and some insurers do this routinely in the U.S., the bulk purchase strategy could also be pursued on a national or regional basis in Africa.

**Importation vs. local production.** Many countries prefer local manufacture of patented and/or generic medicine because it increases economic capacity within an economy and because it reduces balance of payment deficits. Many national patent regimes before TRIPS had local manufacturing requirements that required multinational pharmaceutical companies to build local production facilities at least for finished products. However, because Article 27.1 in TRIPS prohibits discrimination against imports, there is reduced pressure on major manufacturers to locate final assembly plants in developing countries. Brazil still has this local-production requirement in its patent legislation, which is the technical grounds of the U.S. trade complaint to the WTO.<sup>147</sup>

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<sup>145</sup> Sheryl Gay Stolberg & Jeff Gerth, *Medicines Merchants Holding Down the Competition: How Companies Stall Generics and Keep Themselves Healthy*, New York Times (July 23, 2000). <http://www.nytimes.com/library/national/science/health/072300hth-generic-drugs.html> (12/01/00).

<sup>146</sup> Jeff Gerth, *Agency Plans to Study Drug Makers' Records to See Whether Deals Delay Generics*, New York Times (Oct. 12, 2000) <http://www.nytimes.com/2000/10/12/politics/12DRUG.html> (12/01/00).

<sup>147</sup> However, other provisions in TRIPS arguably permit a preference for local production, especially when there has been abuse of intellectual property rights or a persistent failure to transfer technology to the importing country. Article 7, set out objectives of TRIPS to include "the transfer of technology." Similarly, Article 8(2) recognizes that measures may be taken to "prevent the abuse of intellectual property rights" and "the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology." Finally, article 30 provides that member states "may provide limited exceptions for the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a

**Quality control and counterfeits.** The issue of quality control in HIV/AIDS medicines is serious and not all generic manufacturers are created equal. Moreover, there is a latent danger of counterfeit medicines, though there is little direct evidence that the problem is widespread. Although most developed countries have highly functional quality control mechanisms and can conduct quality studies both internally and abroad, most African countries do not have adequate inspection/testing capacity and instead have relied on brand name as a proxy for quality. As Africa relies more and more on generics, it will probably have to increase its ability to monitor manufacturing standards and quality control. However, because it is impractical to think that each small and poorly resourced African country can ratchet its medicines control infrastructure to a high level, there are opportunities for regional solutions. Alternatively, the well-resourced agencies in the North could conduct proxy studies of generics for developing nations or international structures, like the WHO, could assume this responsibility.

**Financing imports with foreign exchange.** Whenever a medicine is being imported from a foreign nation, there will be potential problems in financing foreign exchange. Most developing countries do not have foreign currencies exchange surpluses in dollars, pounds, euros, or yen, and thus they will ordinarily have to borrow foreign currency. If foreign exchange lenders are reluctant to finance such purchases, then the purchases cannot occur because most multinationals are reluctant to accept local currencies from developing nations. Some analysts argue that this will be the major barrier to governmental purchases of large supplies of HIV/AIDS medicines.

**Tariffs.** As a quasi-protectionist or income-generating measure, many countries have high tariffs on imported medicines which significantly raise the costs of life saving medicines. Similarly, value-added taxes can also significantly raise prices to final consumers. In order to encourage affordability of medicines, developing nations will need to reconsider their tariff and taxing policies with respect to essential HIV/AIDS medicines, if possible by creating total tax exemptions.

**Distribution costs and retail pricing.** Another factor that can considerably raise the costs of HIV/AIDS medicines is the number and size of mark-ups in the pharmaceutical delivery market. If the wholesaling industry is concentrated, as it is in some African countries, then wholesalers can impose unreasonably price mark-ups no matter how cheaply drugs are produced or imported. Likewise, if there are multiple stages in the chain of distribution, each of which has overhead costs and profit margins, there can be serial escalation of drug prices as medicines move through the distribution system. Finally, if retail pharmacies are totally unregulated as to their pricing practices, they too can significantly increase the costs of medicines, frequently by 100%.<sup>148</sup> Accordingly, good practice might authorize a modest dispensing fee to pharmacies rather than permit percentage price markups, at least with respect to essential HIV/AIDS medicines.

**Medical insurance and payment schemes.** In the developing world, the great majority of medical purchases are made by poor consumers out of meager savings or through sales of family resources.<sup>149</sup> Even where there are medical aid or insurance schemes, these insurance plans often have benefit limits and exclusions that reduce access to HIV/AIDS medicines. An essential component of increasing access to treatment is to require medical aid programs to increase their HIV/AIDS coverage benefits. Alternatively, the governments can take on the costs of HIV/AIDS treatment within the public health budget, as they sometimes have done with TB and malaria control.

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normal exploitation of a patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties."

<sup>148</sup> Retail pharmaceutical mark-ups are particularly significant in South Africa adding 34% of final cost. Duncan Reekie, *South Africa's Battle with AIDS and Drug Prices 2*

<sup>149</sup> OXFAM, *supra* note \*, at 15-16.

**Employers' and unions' roles.** Related to the issue of insurance is the involvement of employers in the delivery of HIV/AIDS medicines. The most direct connection is that employers can negotiate for insurance that covers HIV/AIDS treatment. Major employers might as well have sufficient market power to buy medicine in bulk. Employers are also well situated to institute HIV testing, counseling, and treatment programs. In addition, they are in a position to improve HIV/AIDS awareness, to decrease stigmatization by insuring employment rights, and to improve living conditions that reduce the incidence of prostitution. South Africa, for example, has passed regulations outlining good practices for employers with respect to HIV/AIDS, but much remains to be done to implement the new mandates. Unions too can organize around these issues and make them part of their labor negotiations. They can also create HIV/AIDS awareness, resources, and clinics within their own structures as COSATU is beginning to do.

**Secure distribution systems.** Governments, medical providers, and consumers have an interest in the security of pharmaceutical storage and distribution systems so that needed medicines get to ultimate consumers. The pharmaceutical industry is especially concerned about the development of an illegal trade in stolen HIV/AIDS medicines provided free or at a discount in Africa. If these medicines were to be exported clandestinely to the U.S. and Europe, then Big Pharma's most lucrative drug markets would be undermined. Accordingly, security is an important multi-party concern. Unfortunately, the existing distribution systems in Africa suffer from a significant degree of corruption and theft. In South Africa, for example, the Pharmaceutical Manufacturers Association has claimed that 50% of all medicines are "lost" in the distribution system, frequently to be sold to corrupt pharmacies where they are resold at discount to cost-conscious payers in the private health care sector. Although there is no concrete evidence of an international black market in pharmaceuticals and although First World consumers are unlikely to buy HIV/AIDS medicines of uncertain origin on street corners, there is some risk that crime cartels could mount a more systematic drug diversion campaign linked to shady pharmacies in the West. Such diversion could effectively double the cost of medicines in Africa and undermine the willingness of major manufacturers to supply high quality goods.

**Medical infrastructure.** The pharmaceutical industry has historically justified its procrastination in providing affordable medicines by deriding the medical infrastructure of African countries. And there is no doubt that there are very significant deficits. As previously mentioned, many of these deficits have been exacerbated by World Bank and IMF structural adjustment policies that caused disinvestment in the public health sector, that required privatization and decentralization of some health facilities, and that imposed fee-for-services and user costs. There were as well stark, racially driven inequities between health services in the private sector that historically served colonial and governmental elites and the public health sector which served the vast majority of black Africans.<sup>150</sup> The net effect is that African countries, including South Africa,<sup>151</sup> have extremely inefficient and tattered public health sectors.

**Trained health workers.** There is as well a lack of human capacity in Africa's health sector. Many qualified medical personnel have left African countries to "greener" and "safer" pastures, some by their own initiative as a form of white (and Indian) flight, others by active recruitment and inducement.<sup>152</sup> In addition, because of a lack of opportunity to treat HIV/AIDS

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<sup>150</sup> According to a Health Portfolio Committee report to South Africa's Parliament on March 13, 2001, spending per patient in the private sector, a generally healthier clientele, is approximately 40% higher than in the public sector.

<sup>151</sup> Within its income class, South Africa has the worst performing health care system in the world, primarily because of stark income inequality. *SA's Health System Rates "Lowest in World"* Independent On-Line (March 14, 2001) [http://www.iol.co.za/general/newsprint.php3?art\\_id=ct20010313214010255H430326](http://www.iol.co.za/general/newsprint.php3?art_id=ct20010313214010255H430326) (3/16/01). See *South African Health Review 2000* (2001) <http://www.hst.org.za/sahr/2000/preface.htm> (3/14/01).

<sup>152</sup> Canada in particular has been ruthless in recruiting South African doctors and nurses.

patients previously and because of deficiencies in medical education and training, many health care workers lack any understanding of the complicated HIV/AIDS medical regimes that are now standard in the First World. Accordingly, there needs to be major investment in transferring medical expertise from countries experienced in treating HIV/AIDS, particularly from Brazil which has operated its model program on a shoestring budget.

**Traditional healers and lay workers.** In order to increase medical capacity and to secure patient cooperation, it will be particularly important to enlist the participation of traditional healers and lay persons, especially in the countryside. Many Africans rely extensively on traditional healers and it will be important to recruit and train these healers about the treatment protocols that will eventually reach their patients.<sup>153</sup> Similarly, Partners in Health and other medical providers in the developing world have had significant success training lay workers to conduct directly observed TB therapy which has substantially increased compliance with the six-month treatment regime. These same workers may be supplemental human resources for the HIV/AIDS treatment team.

**Testing and counseling.** African countries are severely under-resourced to conduct mass HIV/AIDS testing and counseling. Presently, few people seek HIV testing because there is no treatment available and because of fear and social stigma associated with HIV infection in most communities. A huge cohort of health workers will have to be trained in pre-test counseling, rapid testing protocols, and in post-test counseling. Cultural, racial, and gender sensitivity will be important in this counseling as will multilingualism. It will be especially important for the counseling process not to raise false hopes about the effects of treatment on the continuing need to practice safe sex. One of the social complications arising from the newly effective anti-retroviral therapies is that some patients become more unsafe in their sexual practices following introduction of HIV antiviral therapy increasing risk not only to others but to themselves.

**Stigma and rights.** The likelihood that large numbers of infected persons will come forward for testing is slight when the predominant cultural response is stigmatization and loss of rights to jobs, housing, and communal support. Testing and treatment will advance as people living with HIV/AIDS are viewed and treated positively as people whose lives have value and who have positive rights to treatment and social support. However, there is still reluctance, even from people in leadership positions, to acknowledge their HIV-positive status. As long as this status remains closeted, the normalization of the disease will be impeded and the cultivation of compassionate systems of response will be delayed.

**Monitoring.** African countries have few of the sophisticated machines and testing labs that are standard in the North for conducting CD4 blood counts, assaying HIV viral loads, checking liver function, and monitoring drug resistance. In addition, these kinds of tests are quite expensive and could easily double the cost of yearly anti-retroviral treatment.<sup>154</sup> Researchers must accelerate their efforts to discover testing and monitoring protocols that are pragmatically practicable in the chronically under-resourced public health systems of Africa.

**Compliance.** The issue of compliance in HIV/AIDS care is serious because of the ease by which the virus mutates and becomes drug resistant. Many experts wonder whether African masses have sufficient medical understanding to realize the importance of complying with a strict medicine and treatment regime. Moreover, at present, the triple-dose anti-retroviral treatment regime is quite complicated requiring multiple doses of individual medicines and medicines that must or can't be taken with food, etc. However, this degree of complication could be significantly reduced by the production and registration of rational combination medicines.

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<sup>153</sup> It is important as well to remain open to forms of traditional medicine that may provide some relief to people living with HIV/AIDS. Traditional healers have already identified medicines that seem to produce ameliorative effects for AIDS patients.

<sup>154</sup> Belinda Beresford, *Doctors Helpless in the Face of Hidden AIDS Therapy Costs*, Daily Mail and Guardian (March 30, 2001) [wysiwyg://25/http://www.q.co.za/2001/2001/03/30-lead.html](http://www.q.co.za/2001/2001/03/30-lead.html).

Admittedly, the risks of mutations and drug resistance arising from non-compliance are serious, not just for Africa but for the rest of the world. As drug-resistant strains arise, the danger of fresh epidemics increases. However, race-based fears about the ability or willingness of African people to adhere to complicated regimes is countered by research conducted by Partners in Health in Third World conditions where medical compliance at 70% compares favorably to the rate of HIV/AIDS medical compliance in developed countries.

### *LEGAL FRAMEWORK OF ACCESS TO AFFORDABLE MEDICINES*

The essential premise of my analysis is that the project of enhancing access to HIV/AIDS medicines depends on dramatically decreasing the costs of such medicines, on securing sustainable sources of supply, and on finding resources to pay for those medicines. As discussed in the preceding analysis, there are many other factors which effect the ultimate price and effective delivery of high quality medicines, but before those factors become major issues there must be a reliable source of cheap, high quality medicines. Fundamentally, there are seven ways that more affordable medicines can be secured by South Africa and other developing countries where there are pharmaceutical patents. (Some of these strategies are also appropriate to the vast majority of African countries that have no direct patent barriers.) The first three options are dependent on unilateral action or voluntary agreement by the major drug producers and thus are relatively free of legal constraints other than proper registration of the drugs for medical use. That does not mean that these programs do not have differing costs, born by different parties, but the legal framework is relatively slim. These company-driven options are: (1) discounted or tiered-pricing; (2) donation programs, or (3) voluntary licenses to generic companies, African countries, or international organs like the WHO which would tender and secure low-cost generic supplies of HIV/AIDS medicines. The last four options, on the other hand, require governmental action, typically against the express wishes of the pharmaceutical companies, and are subject both to national intellectual property rules and to the international intellectual property regime codified in TRIPS. These possibilities, heavily constrained by legal rules, include: (1) parallel importation of cheaper branded medicines from another country against the wishes of the local patent holder; (2) compulsory licensing to permit local generic production, (3) compulsory licensing to permitting importation of generics, and (4) importation even in the absence of a compulsory license as an Article 30 limited exception to TRIPS. In analyzing these last four options, it will be necessary to provide a brief introduction to the TRIPS agreement and its standard interpretation. Fortunately, there are clearly loopholes and ambiguities in the international intellectual property regime that can be exploited to increase access to essential HIV/AIDS medicines.

### *INDUSTRY CONTROLLED PROGRAMS*

#### *Discount- or Tiered-Pricing*

Discount- or tiered-pricing has been the option favored within the UN and by the U.S. trade representative throughout much of the last decade, and it has become the option increasingly favored by Big Pharma. Under the discount- or tiered-pricing scheme, the major manufacturers set a pricing scheme that is inversely proportional to the development index of the recipient country. Although some advocates see only a limited number of steps, perhaps as few as two, a First World and a Third World price, the industry seems to favor a multi-tier system that would allow it to charge increasingly profitable prices to middle and higher income countries, topping out in the U.S. which has the overall highest pharmaceutical price list in the world. For this scheme to work, consumers in the developed world will have to be convinced that they should subsidize price discounts in the developing world. Already, there is some backlash

emerging in the U.S. about price reductions in Africa, in part because there is still no universal access to affordable HIV/AIDS medicines in the U.S. In addition, for tiered-pricing to work, there would have to be limitations on the resale or redistribution of the discounted drugs back to First World markets. With these two conditions satisfied, the tiered-pricing scheme promises to provide highest quality drugs at some significant discount to African countries. Moreover, because of existing productive capacity, the industry could start supplying significant and growing quantities of medicines almost immediately. Despite these general benefits, there are some particular advantages to the industry and disadvantages to African countries in the tiered-pricing scheme. The big drawback is lack of sustainability because price discounts are voluntary and temporary – the discount can be taken away after the termination of any particular agreement.

<b>ADVANTAGES TO INDUSTRY</b>	<b>DISADVANTAGES TO AFRICA</b>
<p>The biggest advantage is that tiered-pricing leave the intellectual property regime intact.</p> <p>Properly packaged, the tiered-pricing scheme rehabilitates the “AIDS Profiteer” image of the industry.</p> <p>Tiered-pricing does not require disclosure of trade secrets concerning actual costs of production. It might be possible to recapture some fixed costs through creative accounting.</p> <p>In tiered-pricing schemes that admit being above cost, it is possible that a significant quantity of sales could actually increase corporate profits, though not rates of profit.</p> <p>Tiered-pricing permits the industry to maintain brand loyalty.</p> <p>Tiered-pricing also creates barriers to entry of generic producers who must wait until patent expiration to begin manufacture and marketing.</p>	<p>Tiered-pricing does not result in technology transfer or in the development of a local pharmaceutical industry.</p> <p>Tiered-pricing is controlled by the pharmaceuticals and can come with conditions requiring nations to forego other options such as parallel importation or compulsory licenses.</p> <p>Tiered-pricing is not necessary transparent as to actual marginal costs of production. Thus, rock bottom prices may still have cost-recovery features.</p> <p>Tiered-pricing schemes are inherently unstable as the manufacturers can refuse to continue or extend their short-term offers.</p> <p>Tiered-pricing is less likely to apply to new generations of HIV/AIDS medicines.</p>

### *Drug Donations*

Donation programs can result in the immediate delivery of needed medicines at no cost to the receiving nation and thus have immediate short-term benefits. As long as the medicines meet a critical need and as long as they don’t divert medical attention way from higher priority care programs, donations have obvious appeal in the absence of other possibilities. In some instances, companies prefer donation programs to tiered-price programs, particularly because of tax advantages and charitable deduction rules that might make donation programs might even cheaper than price discounts.<sup>155</sup> However, despite a temporary cost benefit, for both parties, there

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<sup>155</sup> Donation programs have tax advantages in the U.S. which ordinarily permits the manufacturer to deduct twice the inventory cost basis of the donated drug. This inventory cost basis, a legal fiction, is often higher than the actual marginal cost of production of the drug. Since twice the maximum corporate tax rate (35%) equals 70%, the donation can be significantly tax subsidized and may actually result in a net financial gain to the donor. See Alain Guilloux & Suerie Moon, *Hidden Price Tags: Disease-Specific Drug Donations: Costs and Alternatives* (Médecins Sans Frontières October 2000).

are advantages to the donor that do not accrue to the donee. Just as with discount pricing schemes, the main drawback to donation schemes is their lack of sustainability.

<b>ADVANTAGES FOR DONOR</b>	<b>DISADVANTAGES FOR DONEE</b>
<p>Donation programs sound extraordinarily generous and ordinarily generate positive publicity.</p> <p>Donation programs can be, and invariably are, time limited, creating long-term flexibility for the industry while providing short-term relief from adverse publicity.</p> <p>Donation programs continue to shield the true production costs of medicines which are often pennies on the dollar.</p> <p>Because the drugs are donated, the companies often have the upper-hand in setting conditions on uses. They can limit the drugs to certain diseases and/or to certain patients.</p> <p>Donation programs preempt the market and delay the development of local manufacturing capacity. Since there are developmental costs and time delays in producing generic drugs, the donation program actually acts as a barrier to entry.</p> <p>Donation programs permit companies to give drugs at or near the end of their shelf life, drugs that they might otherwise have to destroy in the near future.</p> <p>Donation programs permit companies to place restrictions on intellectual property rules in the affected countries, “We’ll agree to give you these drugs only if you agree not to seek a compulsory license, or to parallel import, or to import low-price generics.”</p> <p>Donation programs permit the company to build brand loyalty both with the medical profession and with the patient population.</p>	<p>This publicity impedes the ability of activists and governments to agitate and to negotiate for more viable long-term solutions.</p> <p>Time limitations are the Achilles heel not only because they postpone adoption of long-term strategies, but because they can cause counter-therapeutic interruption of long-term treatment protocols.</p> <p>Without information about true costs, governments can not weigh their alternatives.</p> <p>Conditionalities can distort appropriate medical treatment.</p> <p>Delays in creating a competitive generic industry threatens the development of more sustainable and reliable sources of supply.</p> <p>Constantly monitoring drug expiration dates on short shelf-life medicines is costly and destruction of expired products can lead to interruptions in local supply.</p> <p>Countries are thereby foreclosed from pursuing their strategic interest in long-term solutions.</p> <p>This brand loyalty might create resistance to the introduction of competing generic medicines driving up health care costs.</p>

### *Voluntary Licenses to Produce Medicines*

Voluntary licensing agreements result from negotiations between patent holders and other entities, typically in this context, developing countries, though they can be with other companies as well, including generic manufacturers. Voluntary licensing agreements allow third parties to use a patent holder’s patent to produce, market, or otherwise distribute the patented product normally in exchange for a royalty or licensing fee to the patent holder. In addition to requiring agreed-upon compensation for licensing, the patent holder can ordinarily impose restrictions on the sale or transfer of the license and on the geographical distribution and marketing of the

affected product. Finally, the patent holder can limit the duration of agreement and can even make it terminable at will or revocable on certain conditions. Theoretically, this “voluntary” agreement results from a meeting of minds between equally knowledgeable and equally powerful parties who have outside options to negotiated agreement. In the pharmaceutical context, however, the power, wealth, and information advantages are heavily tilted towards the companies because they own exclusive patents and have trade secrets concerning costs of production. Therefore, pharmaceutical companies can enforce onerous terms on the amount of compensation, permitted usages, and distribution, especially export. Although various experts have urged broader usage of compulsory licenses,<sup>156</sup> to date only one company, GlaxoSmithKline, has granted a voluntary license in sub-Saharan Africa. This license to Aspen Pharmacare in South Africa is exclusive, territorially limited, product limited, and for sales in the public and WHO-approved NGO sector only. Moreover, there is an unusually steep 30% royalty on sales.<sup>157</sup> The most compelling analysis of this license is that it was granted in order to undermine Cipla’s anticipated application for a compulsory license to GSK’s ARV medicines.

<b>ADVANTAGES TO PATENT HOLDERS</b>	<b>DISADVANTAGES TO LICENSEES</b>
<p>As stated, the patent holder can call the shots and negotiates from a position of vastly superior bargaining power.</p> <p>In particular, the voluntary license maintains the patent holder’s intellectual property rights against all others.</p> <p>The one ambiguous limitation on this bargaining power is the provision in TRIPS that permits a country or competitor to seek a compulsory license when the patent holder has not voluntarily granted a license on commercially reasonable terms and conditions. Article 31(b).</p>	<p>The degree of control given to the patent holder creates multiple potential disadvantages to the governmental or non-governmental license.</p> <p>The main disadvantages are market-segment control (public sector only); geographical limitations; price control; and royalty rates. An additional disadvantage is that most voluntary licenses would not permit cross-licensing with other companies to permit production of combination medicines.</p>

### *COUNTRY CONTROLLED PROGRAMS*

According to the dictates of the TRIPS Agreement, the effect of patent protection on pharmaceuticals is that competing companies and developing countries cannot routinely produce, import, or export generic drugs that would infringe the intellectual property rights of the patent holders in either the exporting or importing state. To do so results in costly litigation and actual or threatened trade sanctions by powerful trading partners, particularly the U.S., which until very recently has been extremely aggressive in protecting the interests of the international pharmaceutical cartel.<sup>158</sup> However, there are certain exceptions in TRIPS that allow the "parallel

<sup>156</sup> Jeffrey Sachs calls for differential pricing and voluntary licensing of products to generic producers if the patent-holders choose not to supply at highly discounted prices or if there are “markedly lower costs” in bids by generic producers. *Macroeconomics and Health*, *supra* note \*, at 89. In an open bidding process, if generic producers offers demonstrated significant or marked cost savings, then the patent holder would be urged to license the product to generic producer. However, as Sachs acknowledges, this voluntary license option is non-binding on the patent holder and thus inadequate to secure supply. Thus, Sachs also reluctantly acknowledges the necessity of permitting compulsory licenses. *Id.* at 90.

<sup>157</sup> Press Release, *Aspen Pharmacare Receives Voluntary License from GlaxoSmithKline on Anti-Retroviral Patents in SA*. <http://www.aspenpharmacare.co.za/showarticle.php?id=135> (Oct. 10, 2001). The license does not include abacavir, trizivir, or angenerase, the GSK protease inhibitor.

<sup>158</sup> Patrick Bond, *Globalization, Pharmaceutical Pricing and South African Health Policy: Managing Confrontation with U.S. firms and Politicians* 29 *Int’l J. of Health Services* \* (1999).

importation" of patented drugs from countries where the patented drugs are sold more cheaply or that allow "compulsory licensing", e.g., the permissible manufacture of generic drugs in the affected country upon payment of modest royalty to the patent holder. An alternative use of compulsory licensing would permit the importation of a generic equivalent produced under a compulsory license in the exporting country.<sup>159</sup> A final alternative would permit the production and export of a generic drug to a country without a patent or without productive capacity as a so-called "limited exception" to TRIPS.

### *Human Rights Standards – Access to Health*

The pharmaceutical industry would like to suggest that TRIPS is the only international treaty that impacts the issue of access to medicines. However, people living with HIV/AIDS in Africa have a fundamental human right of access to health, a right that must be used in any proper interpretation of the TRIPS Agreement.<sup>160</sup>

Access to essential drugs is part of the human right to health. Access to essential drugs depends on: (1) rational selection of use of medicines (2) sustainable adequate financing (3) affordable prices and (4) reliable health and supply.... Governments, the UN family, the private sector and civil society each have vital roles and responsibilities in achieving universal access to essential drugs.<sup>161</sup>

Although the actual reality of access to health in developing countries belies the aspiration human rights standard articulated in UN documents, in analyzing interpretive ambiguities in TRIPS, it could be important to remember the competing values codified in international human rights treaties. Similarly, in interpreting the flexibility that South Africa has, both in adopting legislation and in seeking increased access to affordable medicines, lawmakers, judges, and legal activists should be reminded of comparable provisions in the South African constitution:

**Section 10 - Human Dignity:** Everyone has inherent dignity and the right to have their dignity respected and protected.

**Section 11 - Life:** Everyone has the right to life.

**Section 27 - Health Care.** (1) Everyone has the right to have access to - (a) health care services . . . (2) The state must take reasonable legislative and other measures, within its available resources, to achieve the progressive realisation of each of these rights.

### *Public Health Victories in the Doha Declaration*

Despite the generally negative impact of TRIPS on access to medicines, developing countries secured a significant victory in November of 2001 when the Ministerial Conference of the World Trade Organization met in Doha, Qatar. Although the Doha Declaration on the TRIPS Agreement and Public Health is not yet a legally binding "revision" to the text of TRIPS, the Declaration is an important and morally/politically enforceable clarification of four issues: (1) TRIPS "does not and should not prevent members from taking measures to protect public health . . . in particular, to promote access to medicines for all;" (2) member countries are free to

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<sup>159</sup> *AIDS: Patent Rights versus Patient's Rights*, 356 *Lancet* \* (Aug. 5, 2000).

<sup>160</sup> Canadian HIV/AIDS Legal Network & AIDS Law Project, South Africa, *TRIPS and Rights: International Human Rights Law, Access to Medicines, and the Interpretation of the WTO Agreement on Trade-Related Aspects on Intellectual Property* (Nov. 2001).

<sup>161</sup> WHO Policy Perspectives on Medicines: Globalization, TRIPS, and Access to Pharmaceuticals, 5 (March 2001).

determine the grounds upon which compulsory licenses are issued; (3) member countries are free to determine what constitutes an emergency or issue of extreme urgency, these terms clearly encompass the AIDS, TB, and malaria epidemics; and (4) member countries can establish their own "exhaustion" or parallel importation schemes.<sup>162</sup> Public health advocates are particularly gratified at the public health language because it is not just tied to the big three diseases, AIDS, TB, and malaria. Accordingly, countries can adopt medicine access (and medical device) schemes for multiple diseases and thereby dramatically reduce the costs of medicines.

Unfortunately, the production for export to no-capacity countries was left open, but it was acknowledged to be a real problem requiring an expeditious solution before the end of 2002. "We recognize that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We Instruct the Council for TRIPS to find a expeditious solution to this problem and to report to the General Council before the end of 2002."<sup>163</sup> Once again, any resulting language will not be legally binding, but it will be politically binding as a practical matter.

### *Parallel imports*

Parallel importation is importation, without the direct consent of the patent-holder, of a product legally marketed in another country by the patent-holder or by another authorized party. The rationale for permitting parallel importing is to promote price competition for patented products by allowing importation of equivalent patented products marketed at a lower price in another country by or with the consent of the patent-holder. This indirect competition with oneself was thought to increase the likelihood of fair pricing between countries.

In TRIPS terminology, the patent-holder's right to further limit the international movement of a pharmaceutical has been "exhausted" once the product has been marketed by or with the consent of the original patent-holder. Almost all countries have had the principle of internal exhaustion permitting resale within a country; such resale is necessary to the ordinary movement of pharmaceutical products through the wholesale and retail distribution system. In addition, many countries had allowed international exhaustion, meaning that drugs could be imported from a legitimate foreign source once the patent holder or its licensee had made a profit (exhausted its rights) on the original sale of the product. The TRIPS Agreement does not prohibit member countries from adopting the principle of international exhaustion; in fact, it explicitly permits it. Moreover, Article 6 states that disputes relating to exhaustion are not subject to the WTO dispute settlement process.

The pharmaceutical industry is critical of parallel importation practice because it limits companies' ability to charge whatever a local market will bear. It also reduces profits in high price countries if consumers obtain cheaper sources of supply with a lower profit margin elsewhere. However, most developed countries have imposed significant restrictions on parallel importation of medicines. The U.S. prohibits the practice completely, whereas the E.C. permits regional importation only between members of the economic union. In addition, major pharmaceutical companies have several "private" options to circumvent parallel importation rules. The most Draconian would be to impose a uniform high price worldwide thereby decreasing affordability massively in middle-income and low-income nations. But other solutions are more subtle. For example, a company could limit its supply to a low-price country to an amount sufficient for internal consumption only. Alternatively, especially in a price-control

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<sup>162</sup> WT/MIN(01)/Dec/W/2 (Nov. 14, 2001). Although treatment activists have argued that these interpretative openings should have been acknowledged from the beginning, the U.S., and the E.U. to a lesser extent, have insisted nor narrower interpretations on all of the points above.

<sup>163</sup> *Id.* ¶6.

jurisdiction, a company could charge two prices, one for domestic consumption and a second for export products.<sup>164</sup>

Although there are many contexts where legal activists would disapprove of protective anti-parallel pricing practices by multinational pharmaceuticals, prohibitions against parallel export/import probably make sense when a company has been forced to make major price concessions to a particular country or region, as the industry has started to do in Africa. However, a more progressive analysis would not necessarily object to parallel export/import to other developing countries not yet reached by concessionary or discount pricing. OXFAM has addressed this dilemma by proposing that there be one parallel import rule for developing countries and another for developed countries. Although developing countries would be free to parallel import from any cheaper branded source, developed countries would not be permitted to parallel import from nations receiving concessionary pricing.<sup>165</sup>

*Parallel Importation in South Africa*<sup>166</sup>

<b>ADVANTAGES</b>	<b>DISADVANTAGES</b>
<p>Parallel imports are likely to be of high quality and may already satisfy the registration requirements of the importing country.</p> <p>Parallel imports can quickly meet demand.</p> <p>Parallel importation permits drugs to be purchased at their cheapest price through comparison shopping.</p>	<p>To prevent profit loss in high profit markets, patent holders might raise price in lower-price markets creating reduced availability of affordable medicines in developing countries.</p> <p>Pharmaceutical might oppose adopting voluntary discount pricing schemes because of fear of parallel importation back to their high profit First World markets.</p> <p>Parallel importation might result in more counterfeit products and in the sale of products without support or service for that product.</p> <p>The patent holder could easily impose contractual provisions prohibiting the export of the patented product to other markets.</p>

<sup>164</sup> OXFAM, *supra* note \*, at 24.

<sup>165</sup> *Id.*

<sup>166</sup> After a three-year delay resulting from a pharmaceutical industry lawsuit, the possibility of parallel importation has finally been realized. The Medicines and Related Control Act of 1997, in relevant part, reads as follows:

“Measures to ensure supply of more affordable medicines”

15C. The Minister 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-

- (a) notwithstanding anything to the contrary contained in the Patents Act (57 of 1978), determine that the rights with regard to any medicines under a patent granted in the Republic shall not extend to acts in respect of such medicines which has been put onto the market by the owner of the medicine, or with his or her consent;
- (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 registered in the Republic, 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;
- (c) Prescribe the registration procedure for, as well as the use of, the medicine referred to in paragraph (b).

	Pharmaceuticals might lose profits for research and development and/or reduce even further R&D in Third World diseases.
<b>TRIPS</b>	<b>SOUTH AFRICAN LAW</b>
<p>International trade laws ordinarily permit parallel importation because the patent holder has “exhausted” its patent rights, i.e., earned its monopoly profits, in its sale in the exporting country. TRIPS does not address or limit exhaustion principles. Article 6.</p> <p>There are arguments that parallel importation violates Article 28(a) dealing with exclusive rights of importation and/or that it violates Article 27(1) by in effect permitting discrimination against locally produced products. The recent Doha Declaration, however, recognized that member countries are free to establish their own exhaustion rules.</p> <p>Compulsory licenses in exporting countries are ordinarily limited to production “predominantly” for the supply of the domestic market. Article 31(f). The only exception on this limitation is where the license has been granted because of anti-competitive practices. § 31(k). Thus, many holders of compulsory licenses will not be able to export their products.</p>	<p>The Medicines and Related Substances Control Act of 1997, Section 15C(a), authorizes the Minister of Health to prescribe conditions for the supply of more affordable medicines including parallel importation.</p> <p>The Patent Act does not appear to directly address the issue of parallel importation except vis a vis unequal international pricing language in § 56(2)(e).</p>

*Compulsory licensing for domestic production*

Compulsory licensing enables a competent government authority, including a health or patent department, to license the production and use of an invention to an authorized third-party or government agency without the consent of the patent-holder. In the context of AIDS, compulsory licenses could be utilized to stimulate price-lowering competition and to ensure availability of needed medicines, but no African nation has sought, let alone obtained, a compulsory license for HIV/AIDS medicines; however, Cipla has recently applied for compulsory licenses in South Africa to manufacture ARVs. Complicating any such effort is the fact that few developing countries have comprehensive compulsory licensing clauses in their national legislation, though South Africa does. Even as African countries are amending their intellectual property regimes to become TRIPS compliant, many of them are not taking advantage of the compulsory license loopholes that exist, in part because of past threat of U.S. trade sanctions.

The permissible grounds for compulsory licenses are not fully enumerated or delimited in the TRIPS Agreement, and thus African nations still have significant discretion in selecting health sensitive policies especially in the aftermath of the Doha Declaration. Permissible grounds for compulsory licensing may include the public health/public interest broadly defined, problems linked with national emergencies such as epidemics, public non-commercial or governmental use, non-working or insufficient working of the patent, and/or anti-competitive or abusive practices, including unfair pricing. Some of these grounds permit expedited governmental action. For example, when the government declares an emergency<sup>167</sup> or finds another extremely urgent

<sup>167</sup> South Africa has definitively stated that it will not declare a national emergency on account of AIDS because of its alleged implications under its Constitution. However, South Africa remains free to make

circumstance, such as the AIDS pandemic, it could seek a compulsory license for itself, or for an authorized third party, to begin commercial exploitation without first negotiating with the patent holder. Similarly, when the government is seeking or permitting a license for public non-commercial use, the government or its authorized agent is not required to seek prior approval and it can limit the patent-holder's remedies to review of the amount of compensation.<sup>168</sup> Finally, if the government acts to redress anti-competitive practices or abuse of patent, it can both reduce the amount of compensation to the patent holder and can distribute the product outside the domestic market.<sup>169</sup>

Although TRIPS is relatively indifferent about the grounds of a compulsory license, it is relatively strict about the conditions that must be met in order for a license to be granted. Except in cases of governmental use or cases of arising from abuse of rights by the patent-holder or cases involving emergency or extremely urgent conditions, the government is ordinarily required to first seek a voluntary licensee on commercially reasonable grounds for a reasonable period of time.<sup>170</sup> In these more normal public health and public interest circumstances, the government loses its ability to move on an expedited basis. In addition, as previously stated, the government or its authorized third-party is required to pay adequate compensation.<sup>171</sup> Even though the meaning of adequate compensation is not fully defined in TRIPS, the WTO will be certain to look at the process used to reach a particular result. Despite some requirement of case-specific determinations, however, it would certainly be possible to set forth factors affecting the royalty rate including inventiveness, research and development costs, remaining life of the patent, purpose of use, etc. Fortunately, the companies cannot ordinarily insist on receiving their normal, extraordinary rates of profit. Instead, small royalties in the range of 2-10% have become traditional in the pharmaceutical field.<sup>172</sup> Compulsory licenses are ordinarily limited to "predominantly" supplying the domestic market of the authorizing country except in cases of patent abuse.<sup>173</sup>

Even if a compulsory license is granted, the patent-holder retains its underlying intellectual property rights in the patent. The license granted is ordinarily non-exclusive, meaning the patent-holder and its other licensees can still compete;<sup>174</sup> moreover, the license is non-assignable.<sup>175</sup> More significantly, the license is revocable once the circumstances that led to its granting have ceased to exist, though some consideration must be given to the interests of the licensee who may have invested heavily in order to manufacture the licensed product.<sup>176</sup> If the circumstance is excessive pricing, for example, then the patent-holder could simply lower prices to regain its market rights. It is this possibility of revocation that creates barriers to entry in developing countries even in those rare circumstances where they have sufficient drug manufacturing capacity to produce drugs locally.<sup>177</sup>

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alternative findings of an urgent public health emergency that would permit it to bypass the negotiation phase.

<sup>168</sup> Article 42.

<sup>169</sup> Article 31(k).

<sup>170</sup> Article 31(b).

<sup>171</sup> Article 31(h).

<sup>172</sup> Love, *supra* note \*, at 7-9.

<sup>173</sup> Article 31(f).

<sup>174</sup> Article 31(d).

<sup>175</sup> Article 31(d).

<sup>176</sup> Article 31(c) and (g).

<sup>177</sup> As previously mentioned the vast majority of African countries have little or no pharmaceutical production capacity. See OXFAM, *supra* note \*, at 11.

Compulsory Licensing in South Africa for Government Use or Abuse of Patent – Local Production

Two provisions of the Patents Act (Act No. 57 of 1978) permit compulsory licensing. Section 4 permits compulsory licensing for governmental use after a hearing; section 56 permits compulsory licensing for abuse of patent.<sup>178</sup>

<b>ADVANTAGES</b>	<b>DISADVANTAGES</b>
Local production guarantees continuity of supply and permits easier testing of manufacturing processes and product safety.	The granting of compulsory licensing for local production might discourage foreign investment, retard transfer of technology, including technology necessary for local production, and inhibit research and development particularly R&D into the epidemic diseases of Africa such as HIV/AIDS, malaria, and TB.
Local production builds local economic capacity, economic activity, and employment, particularly of skilled labor.	
Local production eases balance of payment problems and typically keeps wealth and profits in-country where they might be invested to create even more economic capacity.	The quality of licensed production might also be problematic especially in countries that otherwise lack adequate resources and expertise for testing product quality and compiling reports of adverse effects.
Local production increases the breadth and therefore	

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Section 4. State bound by patents. – A patent shall in all respects have the like effect against the State as it has against a person: Provided that a Minister of State may use an invention for public purposes on such conditions as may be agreed upon by the patentee, or in default of agreement on such conditions are then determined by the commission [of Patents] on application by or on behalf of such Minister and after hearing the patentee.

Section 56. Compulsory licence in case of abuse of patent rights.-

- (1) Any interested person who can show that the rights in a patent are being abused may apply to the commissioner in the prescribed manner for a compulsory licence under the patent.
- (2) The rights in a patent shall be deemed to be abused if-
  - (a) the patented invention is not being worked in the Republic on a commercial scale or to an adequate extent, after the expiry of a period of four years subsequent to the date of the application for the patent or three years subsequent to the date on which that patent was sealed, whichever period last expires, and there is in the opinion of the commissioner no satisfactory reason for such non-working;
  - (b) . . . . .
  - (c) the demand for the patented article in the Republic is not being met to an adequate extent and on reasonable terms;
  - (d) by reason of the refusal of the patentee to grant a licence or licences upon reasonable terms, the trade or industry or agriculture of the Republic or the trade of any person or class of persons trading in the Republic, or the establishment of any new trade or industry in the Republic, is being prejudiced, and it is in the public interest that a licence or licences should be granted; or
  - (e) the demand in the Republic for the patented article is being met by importation and the price charged by the patentee, his licensee or agent for the patented article is excessive in relation to the price charged therefor in countries where the patented article is manufactured by or under licence from the patentee or his predecessor or successor in title.
- (3) The patentee or any other person appearing from the register to be interested in the patent may in the prescribed manner oppose the application.

<p>the long-term viability of the national economy.</p> <p>Local production engenders more pride and ownership of HIV/AIDS treatment measures.</p> <p>If multiple compulsory licenses were combined, local manufacturers could produce and register combination medicines that would ease patient compliance with complex treatment regimes.</p>	<p>Compulsory licensing for local production may not be possible in certain countries that lack pharmaceutical capacity and/or investment and human capital. Moreover, these barriers to entry are certain to extend the time within which drugs can be manufactured, thereby delaying effective responses to true public health emergencies.</p> <p>Local markets may be too small to achieve any real economies of scale making local manufacture impracticable.</p> <p>Products manufactured under compulsory licensing may enter a gray market back in the First World thereby reducing pharmaceutical profit margins and research and development into new medicines.</p>
<b>TRIPS</b>	<b>SOUTH AFRICAN LAW</b>
<p>TRIPS specifically prevents special patent rules for a field of technology, such as pharmaceutical products and from discriminating between products that are produced locally and those that are imported. Article 27(1).</p> <p>TRIPS Article 31 expressly permits compulsory licensing on grounds to be determined by each Member Country. However, TRIPS distinguishes procedures to be followed under different conditions and sets certain conditions including appellate review, non-exclusivity, and reasonable compensation.</p> <p><u>Mentioned Grounds:</u></p> <ol style="list-style-type: none"> <li>1. Anti-competitive practices, e.g., excessive prices and other market defects (does not require prior negotiation for voluntary licensing nor is license limited to domestic market, i.e., product can be exported). § 31(k). Note: § 8(2) also specifically sanctions measures designed to prevent “abuse of intellectual property rights.”</li> <li>2. National or extreme emergency (does not require prior negotiation for voluntary licensing but does require prompt notice and is presumed to be of short rather than chronic duration). § 31(b).</li> <li>3. Public non-commercial, e.g., governmental use (does not require prior negotiation for voluntary licensing; can be granted to government contractor as well as government itself). § 31(b).</li> </ol> <p><u>Other Grounds Requiring Attempts to reach Voluntary Agreement:</u></p> <ol style="list-style-type: none"> <li>1. Refusal to deal (when the patent holder refuses a voluntary license on reasonable commercial terms where availability is limited or the development of commercial activity is</li> </ol>	<p>The Patent Act (Act 57 of 1978 as amended), Section 56 provides for compulsory licensing of patented products if the patent is being “abused.” Abuse of patent is defined to cover four circumstances that might apply to the HIV/AIDS context:</p> <ol style="list-style-type: none"> <li>1. The patented product is not being worked in the Republic on a commercial scale or to an adequate extent. § 56(2)(a). Query: is the patent being adequately worked when the supply is grossly inadequate to the need?</li> <li>2. “The demand for the patented article in the Republic is not being met to an adequate extent and on reasonable terms.” § 56(2)(c). Here the argument would be that affordability is a central to adequate supply and that reasonable price is an important term. There is no doubt that the demand for HIV/AIDS drugs greatly exceeds its affordable supply.</li> <li>3. By the refusal of the patentee to grant a (voluntary) license upon reasonable terms whereby actual or prospective trade or industry is prejudiced and a compulsory license would be in the public interest. § 56(2)(d). It might be possible to argue that the public health and health sectors are being prejudiced by the absence of reasonably affordable HIV/AIDS medicines, especially combination pills. Cipla had requested voluntary licenses before it applied to South Africa’s competition authority for compulsory licenses.</li> <li>4. In cases of importation, the imported product is excessively priced compared to patented or licensed products sold in other markets. § 56(2)(e). Some HIV/AIDS medicines are sold much more cheaply where they face competition. Moreover, certain HIV/AIDS drugs may be cheaply manufactured under compulsory licenses.</li> </ol>

<p>negatively affected)</p> <p>2. Lack or insufficient working of the patent, e.g., not making the product available.</p> <p>Public interest broadly defined. Note: The Doha Declaration acknowledged that Article 8(1) permits adoption of measures necessary to promote public health.</p>	<p>The South Africa Constitution § 25 provides for expropriation of private property (including patents) for a public purpose subject to compensation. Similarly § 4 of the Patent Act permits any Minister of State to use an invention for public purposes, preferably by voluntary agreement, but otherwise by compulsory licensed issue after application and hearing.</p>
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*Export/Import of generics under compulsory license*

Compulsory licensing permitting local production is an illusory right for most African countries that lack the industrial capacity to produce HIV/AIDS medicines, unless there are also provisions that permit the importation of cheaper generics. It is estimated that only twelve developing countries, most notably India, have pharmaceutical industries capable of duplicating base ingredients and manufacturing inexpensive equivalents of patented medicines.<sup>179</sup> Fortunately, as previously mentioned, most HIV/AIDS medicines are not presently patented in most African countries and thus they could immediately seek to import low-cost generics, licensed or not, without running afoul of TRIPS, assuming that such generics could be legally produced and exported from the producing country. However, other countries, most especially South Africa, have received patent applications for virtually all of the essential HIV/AIDS medicines.

In South Africa, it might be a better public policy and resource option to import high quality, generic products, such as those offered by Cipla, rather than try to produce them locally. As previously discussed, there may be important economies of scale and thus significant price savings for high volume generic production. Since Cipla has already applied for a compulsory license citing abuse of patent by the patent holders, thereby potentially forcing the South African government to do something it has previously neglected to do, there is a real possibility that South Africa too would be permitted eventually to import drugs from India.

The problem is that TRIPS does not ordinarily permit the competing importation of a patent-infringing, non-licensed product. Moreover, production under a compulsory license issued in another nation is ordinarily granted to predominantly supply that domestic market only.<sup>180</sup> Fortunately, there is a domestic-market exception when a patent-holder has been found to have abused its patent, by excessive pricing or otherwise, in the producing country. In these circumstances, a generic producer operating under a compulsory license could produce on a large scale for export. More directly, however, since the TRIPS Agreement provides for non-discrimination between locally produced and imported products, a compulsory license could be granted in the importing country that could in turn be satisfied by an exporting manufacturer such

<sup>179</sup> OXFAM, *supra* note \*, at 10. In Africa, only Egypt can currently produce therapeutic ingredients and finished products, though several other countries, including South Africa and perhaps Kenya, can produce finished products from imported compounds.

<sup>180</sup> For purposes of this analysis, the most problematic feature of the compulsory license regime in TRIPS is that compulsory licenses are authorized “predominantly for the supply of the domestic market” of the authorizing country, except in cases of patent abuse where the limit does not apply. The meaning of this “domestic supply” requirement is inherently unclear as it might mean that “the predominant portion of products produced must be consumed domestically” or alternatively that “the license shall be predominantly for the benefit of domestic consumption.” With the latter interpretation, a country would be justified in exporting a major portion of its production if such export were necessary in order to have large production runs so as to efficiently supply the domestic market. This is the preferable interpretation because it could result in a regional manufacturer being able to supply several small markets in order to achieve cost efficient economies of scale.

as India or Brazil, assuming the producer/exporter does not violate patent rights in the exporting state.<sup>181</sup> Likewise, if parallel importation rules survive, an alternative strategy would be to parallel import drugs produced under a compulsory license issue in another country where the patent-holder has already received compensation and thus has exhausted its rights.<sup>182</sup> In this analysis, even if there is no compulsory licensing in the importing state, the parallel importation would be TRIPS compliant.

*Compulsory Licensing in South Africa – Generic Importation*

<b>ADVANTAGES</b>	<b>DISADVANTAGES</b>
<p>Compulsory licenses to import generics can immediately meet demand in a public health emergency such as HIV/AIDS depending on the manufacturing capacity of the foreign generic producers.</p> <p>With sufficient economies-of-scale based on large demand from multiple nations, generic producers ought to be able to produce HIV/AIDS medicines at greatly reduced prices (subject to countervailing possibility of abusive monopolistic pricing practices).</p> <p>Larger manufacturers might be able to establish more efficient product distribution systems.</p> <p>Compulsory licenses can be issued on the basis of reasonable price controls and narrow profit margins.</p> <p>Multiple compulsory licenses can be combined to ensure development and registration of rational combination medicines that will ease patient compliance with treatment regimes.</p>	<p>Foreign manufacture does not increase local pharmaceutical capacity and economic self-reliance.</p> <p>There is some risk that major pharmaceuticals might simply buy out low-profit competing generic manufacturing eliminating established sources of supply.</p> <p>Where the source of supply would be a licensee or distributor of the patent holder, there is a possibility that the patent holder would impose contractual provisions prohibiting the export of the patented product.</p> <p>Non-consensual generic production will be increasingly difficult for drugs patented after 1995.</p>
<b>TRIPS</b>	<b>SOUTH AFRICAN LAW</b>
<p><u>See discussion above.</u> TRIPS does not expressly restrict the possibility that a compulsory license may be satisfied or executed by means of the</p>	<p>Section 15C(a) of the Act, authorizes the Minister of Health to prescribe conditions for the supply of more affordable medicines. Although the Act does</p>

<sup>181</sup> TRIPS clearly authorizes the issuance of compulsory licenses and Article 27.1 provides for non-discrimination between locally produced and imported products. Article 27.1 surely justifies satisfying a compulsory license through import as well as by local manufacture.

<sup>182</sup> There are arguments that drugs produced under a compulsory license, where a royalty has been paid, have “exhausted” the patent holder’s patent rights. Thus, if parallel importation rules survive, a country that recognizes “international exhaustion” would be permitted to import drugs produced under a compulsory license issued in another country. In this analysis, even if there is no compulsory licensing in the importing state, the parallel importation would be TRIPS compliant. Carlos Correa advocates this approach, *Integrating Public Health Concerns into Patent Legislation in Developing Countries*, Section X.2 (2000).

Although this might apply in some circumstances, it does not apply to Cipla, which has no compulsory license but is instead producing under permissive Indian patent law which is still non-TRIPS compliant. Cipla will be able to continue its production of HIV/AIDS medicines patented before 1995 indefinitely into the future, but may not be able to do so with respect to post-1995 medicines if the patent holder has filed a patent request thereby invoking the “mailbox rule.”

<p>importation of the patented product. Indeed, TRIPS might be interpreted specifically to permit importation from a compulsory licensee in another country, subject to certain limitations. The main limitation is that compulsory licenses in exporting countries are ordinarily limited to production “predominantly” for the supply of the domestic market. Article 31(f). The only exception on this limitation is where the license has been granted because of anti-competitive practices. § 31(k).</p> <p>Note: There is a limited exception to patent rights under Article 30 might expand the right of production for export so long as the exception did not unreasonably conflict with normal exploitation of a patent and did not unreasonably prejudice the legitimate interests of patent owners, taking into account the legitimate interests of third parties.</p>	<p>not specifically refer to compulsory licensing, nor the traditional terms for imposing compulsory licensing, it has been interpreted by some advocates to give high administrative power to the Secretary of Health to order compulsory licensing and importation of essential HIV/AIDS medicines.</p> <p>The Patent Act expressly authorizes compulsory licenses and does not stipulate that they must be granted only to domestic entities. Presumably South Africa could take a compulsory license for government use and then supply that license by means of a foreign generic producer. Alternatively, it could grant Cipla’s application for a compulsory license permitting it to import its generic medicines.</p> <p>Note: Any imported medicine would have to be approved by the Medicines Control Council.</p>
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*“Limited” exceptions for export/import under Article 30*

A more coherent approach for expanding production for export (under a compulsory license or otherwise) is to recognize “limited” Article 30 exceptions designed to address external public health needs. Although the ultimate scope of Article 30 is unclear, particularly in its relationship to Article 31, although its language contains multiple interpretive ambiguities, and although its potential reach has been narrowly construed in at least one WTO decision, there are sound policy reasons and interpretive principles which support using Article 30 to prevent a Catch-22 that bars meaningful import access to medicine for countries most in need of lowest cost generics exported from a producer nation.

The text of Article 30 certainly evidences enough flexibility to justify limited exceptions designed to address the dire public health crises of the developing world:

Members may provide *limited* exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not *unreasonably* conflict with a normal exploitation of the patent and do not *unreasonably* prejudice the legitimate interests of the patent owner, *taking into account the legitimate interest of third parties*. (Emphases added.)

As a guiding interpretive principle post-Doha, it is important to recognize that Article 8 authorizes member countries to consider public health and public interests needs when drafting their patent laws “provided that such measures are consistent with the provisions of this Agreement.” Similarly, Article 7 provides that intellectual property rights “should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users . . . in a manner conducive to social and economic welfare, and to a balance of rights and obligations.” For these two provisions to mean anything, they must mean that member states can balance their public health, public interest, and consumer needs in some affirmative way that impacts the unfettered exercise of patent rights. Thus, given the extent of the AIDS pandemic in Africa and given the realities that many developing countries cannot produce medicines locally, it makes common sense under public health, trade, and human rights principles to fashion limited exceptions that permit the export\_import of AIDS medicines to those poor nations.

The direct language of Article 30 supports an interpretation that *some* significant impact on patent rights is permissible. For example, the first requirement of Article 30 is that the exception must be limited. Although “limited” does not mean that total abrogation of patents would be permitted, it must mean that some impact is possible, such as the quite significant

impact of the “Bolar” exception, which can accelerate approval of generic competition by as much as three years costing the patent holder millions, even billions, of dollars. Similarly, the second and third clauses of Article 30 permit some conflict with the normal exploitation of a patent, though not an “unreasonable conflict,” and some prejudice to the legitimate interests of the patent owner, though not “unreasonable prejudice.” Lawyers are used to talking about the meaning of what is “unreasonable,” but once again the language necessarily suggests that some conflict and some prejudice is permissible – so long as the limited exception does not go too far.<sup>183</sup> In these last two exceptions, there is no real curtailment of the patent holder’s rights in the consuming country. If that country had manufacturing capacity, it could produce medicines own its own. Since it doesn’t, these two proposals simply give no-capacity countries a legal source of off-site manufacture leveling their playing field vis-à-vis countries with productive capacity.

As to the concern that a limited exception should not be used to “substantially curtail” an enumerated right,<sup>184</sup> it is important to emphasize that brand manufacturers have no patent rights in no patent countries. Moreover, in the AIDS context there is no real market for brand name medicines in disease-burdened countries,<sup>185</sup> even at discounted prices in the \$900-\$1500 range. These prices are totally beyond the reach of the poorest and smallest countries of Africa and the countries burdened by an astronomical rate of infection. Thus, manufacturing medicines, with or without a compulsory license, and supplying an export market with lower cost generic medicines does not “take” anything away from current patent holders, especially because they continue to retain the right to produce and sell their medicines.

Fortunately, the language of Article 30 does not suggest that only the patent holder’s rights be considered; it requires that the exception be judged “taking account of the legitimate interests of third parties” including presumably millions of poor people living with HIV/AIDS. There is no geographical scope given about “third parties” who count, and thus the legitimate interests of third parties living in the heart of the pandemic weigh heavily. This last proviso strongly suggests that Article 30 incorporates a principle of proportionality such that if the public health interests of third parties are substantial, then a more significant limitation on patent rights is permissible. In the real world, if these “third parties” in Africa do not get the lowest-price, highest-quality generics available (and foreign aid and debt relief as well), they *will* die. Fortunately, Article 30 can be interpreted to support three highly important means of getting high quality, lowest cost generic medicines to developing countries suffering public health crises, most obviously HIV/AIDS, TB, and malaria.

First, Article 30 could justify manufacture and export of medicines to satisfy a compulsory license issued in the importing country/export market. Because such a license provides for a royalty payment to the patent holder, the patent holder’s legitimate interest are fully protected. This limited exception, first proposed in the so-called Amsterdam Statement to WTO Member States on Access to Medicines,<sup>186</sup> has subsequently been endorsed by the Trans Atlantic Consumer Dialogue in three separate documents: (1) ¶ 3 of TACD’s Resolution on Global Access to Health Care,<sup>187</sup> (2) ¶ 5 of TACD’s Access to Medicines in Developing

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<sup>183</sup> Weissman, *supra* note 7, at 1096.

<sup>184</sup> In *Generic Medicines*, *supra* note \*, the WTO panel found that manufacture before patent expiration so as to register a medicine, the so-called “Bolar” exception was lawful, but that a six-month stock-piling rule was unlawful. In particular, *Generic Medicines* held that any exception which resulted in a “substantial curtailment of [any exclusionary right] cannot be considered a limited exception.” *Id.* at ¶ 7.44.

<sup>185</sup> At present, pharmaceutical sales to Africa constitute only 1.3% of global sales for the proprietary drug industry. As previously stated, less than .1% of Africans with HIV are currently on anti-retroviral therapy.

<sup>186</sup> *Increasing Access to Essential Drugs in a Globalised Economy Working Towards Solutions* (Nov. 25-26, 1999) <http://www.cptech.org/ip/health/amsterdamstatement.html> (accessed Nov. 1, 2001).

<sup>187</sup>

¶ 3. The US and the EU should communicate to the WTO TRIPS council that they will support policies to ensure that compulsory licensing of medicines will also benefit small market countries.

Countries,<sup>188</sup> and (3) Pharmaceutical Doc. No. Health 11-01.<sup>189</sup> It is also endorsed by the Africa Group and its allies.<sup>190</sup> Although this option is critically import to countries where patents are on file and where national legislation authorizes compulsory licenses and where compulsory licenses have been issued, this compulsory-license option does not address the needs of countries that lack compulsory licenses because no patents are on file, including most smaller African markets. Fortunately, there are two other limited exceptions under Article 30 that address this other area of need.

Where a manufacturer is already producing medicines under a compulsory license issued in the country of manufacture, Article 30 could justify the expansion of that compulsory license to permit public-health oriented export, in effect creating a humanitarian exception to the domestic market rule in Article 31(f). In this instance, the patent holder's legitimate interests would be protected by a royalty paid by the compulsory licensee in the exporting state. Using this limited exception, if South Africa were to issue a compulsory license, it could expand that license to supply a regional African market, including countries with no patent in force. Some commentators express disagreement about the relationship between Articles 30 and 31 and about the use of Article 30 to limit one of the enumerated "exclusive" rights of the patent-holder under Article 28. These disagreements impact on whether Article 30 can ever be used so as to facilitate the operation of a compulsory license in either the importing or exporting country so as to permit export to developing countries that cannot manufacture medicines on their own. The better interpretation of the relationship between Articles 31 and 30, however, is that an Article 30 limited exception can be used to augment or expand rights of exportation.<sup>191</sup>

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Specifically, that mechanisms to enable production of medicines for export markets will be supported where such exports benefit public health and where the legitimate rights of patent owners are protected in the markets where the products are used.

<http://www.tacd.org/cgi-bin/db.cgi?page=view&config=admin/docs.cfg&id=107> (accessed Nov. 1, 2001).

<sup>188</sup>

¶ 5. TACD asks the US and the EU to support patent exceptions for the export of medicines.

The EU and the US should send communications to the WTO supporting interpretations of WTO Agreement on Trade Related Aspects of Intellectual Property (TRIPs) provisions that would permit patent exceptions for production of medicines for export, when the legitimate rights of patent owners are protected in the export market. For example, patent exceptions should permit the production and export of a medicine to a country that had issued a TRIPs compliant compulsory license for medicine. A failure to address this issue will substantially undermine the usefulness of compulsory licensing of medicines in countries with small domestic markets.

<http://www.tacd.org/cgi-bin/db.cgi?page=view&config=admin/docs.cfg&id=34> (accessed Nov. 1, 2001).

<sup>189</sup>

REGARDING PATENTS AND EXEMPTIONS FOR EXPORTS:

Agree that a country may provide exemptions to patent rights to companies who are exporting the product to another country where patent rights have expired or where patent rights have been licensed under compulsory licensing and the legitimate interests of the patent owner has been protected under Article 31 of the WTO Agreement on Trade Related Aspects of Intellectual Property (TRIPs Agreement).

<http://www.tacd.org/cgi-bin/db.cgi?page=view&config=admin/docs.cfg&id=111> (accessed Nov. 1, 2001).

<sup>190</sup> Africa Group Submission to the WTO TRIPs Council, ¶ 5 (September 11, 2001).

<sup>191</sup> The specific issue I am considering is this: Does the "other use" language in footnote 7 mean that Article 30 cannot be utilized to expand compulsory licenses in specific circumstances, e.g., to create a limited exception to the "predominantly for domestic use" rule of Article 31(f) so as to supply no capacity and no patent countries in need of lowest cost, high quality generic medicines. Under one interpretation, "other use" means that Article 30 may not be used to expand Article 31 compulsory licenses. [Query: Does it make sense that Article 30 can reasonably limit some patent rights, e.g., manufacturing for drug registration and approval (the Bolar exception), but that it cannot be used to limit patent rights that exist or

An alternative limited exception under Article 30 would permit public-health oriented production and export even in countries where a patent is in force and even if no compulsory license has been issued, but only if the market for those exports were to countries with no patent in effect.<sup>192</sup> This last exception provides even more access to medicines for the many smaller and poorer African markets where patent holders have not even bothered to file or prosecute a patent application and thus where there are no grounds to issue a compulsory license. This exception also expands the potential pool of supplier beyond those manufacturing under a local compulsory license. Because the patent holder has no rights in the importing country, its legitimate interests

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remain despite the issuance of a compulsory license?] Under a second interpretation, "other use" can mean a use other than a use specifically conveyed by a compulsory license, but including possibly a use that is supplemental to or in addition to a right under a compulsory license.

With this interpretation, Article 30 could be used directly, under limited and reasonable circumstances, to expand an article 31 compulsory license, i.e., create another, supplemental use, specifically a right to expanded export beyond that otherwise permitted by Article 31(f). The main argument for the lack of interaction between Articles 30 and 31 arises from the WTO decision in *Generic Medicines*, *supra* note \*, particularly paragraph 7.91, which reads as follows:

The Panel was unable to agree with Canada's contention that Article 27.1 did not apply to exceptions granted under Article 30. The text of the TRIPS Agreement offers no support for such an interpretation. Article 27.1 prohibits discrimination as to enjoyment of "patent rights" without qualifying that term. Article 30 exceptions are explicitly described as "exceptions to the exclusive rights conferred by a patent" and contain no indication that any exemption from non-discrimination rules is intended. A discriminatory exception that takes away enjoyment of a patent right is discrimination as much as is discrimination in the basic rights themselves. The acknowledged fact that the Article 31 exception for compulsory licences and government use is understood to be subject to the non-discrimination rule of Article 27.1, without the need for any textual provision so providing, further strengthens the case for treating the non-discrimination rules as applicable to Article 30. Articles 30 and 31 are linked together by the opening words of Article 31 which define the scope of Article 31 in terms of exceptions not covered by Article 30.<sup>fn</sup> Finally, the Panel could not agree with Canada's attempt to distinguish between Articles 30 and 31 on the basis of their mandatory/permissive character; both provisions permit exceptions to patent rights subject to certain mandatory conditions. Nor could the Panel understand how such a "mandatory/permissive" distinction, even if present, would logically support making the kind of distinction Canada was arguing. In the Panel's view, what was important was that in the rights available under national law, that is to say those resulting from the basic rights and any permissible exceptions to them, the forms of discrimination referred to in Article 27.1 should not be present.

<sup>fn</sup> Article 31 is titled "Other Use Without Authorization of the Rights Holder", and footnote 7 to Article 31 defines "other use" as "use" (derogations from exclusive patent rights) other than that allowed by Article 30.

This paragraph by no means directly addresses the issue of whether Article 30 could be used to create a limited exception to the Article 31(f) domestic use rule. Not only does the paragraph not "hold" that this is an impermissible "interaction" between Articles 30 and 31, it arguably barely even addresses this topic except by the sentence "Articles 30 and 31 are linked together by the opening words of Article 31 which define the scope of Article 31 in terms of exceptions not covered by Article 30." Of course, that is the language of Article 30 and footnote 7. But, the dispute panel was not deciding the permissible use of Article 30 to slightly expand the rights of a compulsory license issued under Article 31. At best paragraph 7.91 is weak *dicta*.

<sup>192</sup> The Africa Group and its allies have proposed this exception in ¶ 9 of their Submission to the WTO TRIPS Council, *supra* note 39. This interpretation is also being advanced by several NGOs, including James Love at the Consumer Project on Technology. James Love, *Access to Medicine and Use of Patents Without the Permission of the Patent Owner: Models for State Practice in Developing Countries*, ¶15-Four (draft 2001).

(none) are fully protected, even though it is entitled to no royalties with respect to these sales. Although manufacture and export might seem to technically violate the patent-holder's Article 28 rights in the exporting country, this limited exception does no real harm in the manufacturing market because the medicines cannot be sold domestically nor could they be sold anywhere else where a competing patent is on file.

In general terms, Article 30 should be understood as supporting public health exceptions with respect to medicines and other medical products. It could for example be used not only to expedite the distribution of essential medicines in response to existing patterns of infectious diseases like HIV/AIDS, TB, and malaria, it could also be used to justify export of medicines in response to bio-terrorism. In order for any of these Article 30 limited exceptions to be lawful, however, there must be enabling legislation in the exporting country permitting Article 31 and/or Article 30 manufacture for export. There must also be some provision for issuance of compulsory licenses in the importing nation, at least with respect to medicines under patent. Finally, there must be expedited processes for registration of medicines, including proof of bio-equivalence. This necessity should support an Article 30 exception to non-disclosure of clinical test information otherwise protected by Article 39.

### CONCLUSION – A CALL TO ACTION

The aggressive disregard in the North of the health status of poor people in the South, particularly poor black people living with HIV, is a scandal that must be addressed by legal and non-legal activists here and abroad. Activists must seek national and international public policy, public health, and legal initiatives that reduce African debt, that promote sustainable economies and income redistribution, and that guarantee low-cost and no-cost HIV/AIDS treatment in a reinvigorated African public health sector. Similarly, although alleviating poverty will not eliminate AIDS, condoning and intensifying poverty certainly makes the pandemic worse. Even if AIDS can't be eradicated by poverty alleviation, focused poverty reduction campaigns, particularly those aimed at reversing the feminization of poverty in Africa, can have a positive effect. Likewise, focused campaigns to improve medical/public health capacity, to reduce mother-to-child transmission, to treat HIV infection with affordable anti-retrovirals, and to treat opportunistic AIDS conditions with essential medications will improve the lives of 28 million Africans living with HIV/AIDS and help reduce the exponential spread of this viral plague.

In fighting for access to essential AIDS medicines worldwide, treatment activists must know their enemy. They must also be strategic in assessing the movement to date and the future political arena of struggle. As a modest step in promoting the activist campaign, I offer the insights below into the interests of the pharmaceutical industry, on the outlines of a new multinational corporate complicity campaign, and into strategic issues confronting the access to medicines movement. At the end, I outline several specific campaign objectives that might help alleviate the global AIDS pandemic and reverse the excess of neo-liberal poverty intensification.

#### *The Contours of a Continuing Pharmaceutical Campaign*

Without attempting to address more global attack on TRIPS, I would like to address a few "pragmatic" issues that might inform a continuing pharmaceutical campaign for treatment activists.

#### Demanding Voluntary Licenses?

Some activists have argued that the drug companies should grant unconditional, non-exclusive voluntary licenses on HIV/AIDS medicines and medical supplies for the remaining life of the subject patents, possibly to international, multi-lateral organizations like the WHO which

would thereafter subcontract with existing generic manufacturers or to generic producers in countries like South Africa which might thereby boost their existing pharmaceutical capacity. Voluntary licenses would require royalty payments to the patent holders, but such payments are likely to be relatively negligible, e.g., 5% or less. To date patent holders have been reluctant to issue voluntary licenses to generic producers and in the one instance they have done so, to AspenPharmacare in South Africa, GSK imposed territorial, private market, and royalty conditions that have rendered the license worthless. Any demand for voluntary licenses must leave no wiggle-room for the imposition of such negative restriction. However pharmaceutical companies might convincingly argue that export should be regional only and under no circumstances should export be permitted back to developed markets in the North even under parallel importation/international exhaustion rules.

The advantages of voluntary licenses held by WHO or another similar entity is that WHO could subcontract production and distribution of lowest priced generic medicines produced most cheaply pursuant to massive economies of scale. In essence, bulk procurement would be accomplished via a small number generic subcontractor, presumably in the present context, Indian manufacturers. Over the long term, the bargaining power of the generic subsidiaries might increase to the extent that there were very few large-scale producers of HIV/AIDS medicines. A single source solution, in particular, would inevitably discourage development of pharmaceutical capacity in multiple developing countries.

The advantages of voluntary licenses for developing countries are: (1) they could be negotiated quickly without reliance on expensive and time-consuming administrative or judicial procedures, (2) they are premised on demands against the industry, (3) they could support transfer of technology and local economic development/diversification, (4) they could result in more sustainable supply, and (5) they could permit exportation to developing countries. (Of course, the failure of a patent holder to grant a voluntary license on commercially reasonable terms is a necessary step in the issuance of compulsory licenses except those taken for governmental, non-commercial use, for emergencies or matters of extreme urgency, or for anti-competitive abuse of patent.) The disadvantages of voluntary licenses to developing countries are: (1) the patent holder is under no compulsion to grant a voluntary licenses, though the possibility of a compulsory license does exert some pressure, (2) the developing country will have to develop pharmaceutical and human capacity with the risk of delay and burden of capital and educational outlays, (3) the local industry is likely to become monopolistic which exerts upwards pressure on prices in the long run in the absence of price controls, and (4) politically, the costs of delay, interrupted supply, and mismanagement fall on the country licensee.

Voluntary licensing actually has some benefit for the patent holder, assuming that it can impose conditions against parallel importation or export to First World markets. In particular, voluntary licenses free the patent holder from some of the negative publicity associated with discounted prices, tax-subsidized give-aways, etc. Essentially, the patent holder keeps its lucrative First World market, makes a minor royalty off developing country sales, and is relieved of the burden of being targeted as a roadblock to more affordable medicines.

As a pragmatic solution, voluntary licenses have some appeal, especially since they are not as threatening to Big Pharma. Although widespread reliance on voluntary licenses reduces market expansion into developing markets to some degree, a voluntary license regime does not undermine the intellectual property regime writ large nor does it prohibit continuing market exploitation for non-HIV/AIDS, TB, and malaria medicines. Activists might like this campaign as well because it targets pharmaceutical companies, which have learned hard lessons about being the bad guy, and thus victories are possible. Activists could pursue voluntary license campaigns through divestment/shareholder activist campaigns and through direct action at drug companies. Despite these potential advantages to a voluntary license campaign, most of the leading treatment activists in the U.S., e.g., Health GAP and CP Tech, have foresworn this issue because it puts too

much power in the hands of the companies and delays a more desirable campaign designed to develop a truly competitive generic alternative.

### Demanding Authorization of Compulsory Licenses and TRIPS Reform

No African country has yet issued a compulsory license for pharmaceuticals, though as previously stated an application by Cipla is pending in South Africa. In fact, many African countries do not yet have national legislation even authorizing TRIPS compliant compulsory licenses, though South Africa is an exception. Moreover, few African countries could tolerate the delay and costs of litigating compulsory licenses in court and even administrative procedures could be time-consuming and onerous. Despite these realities, most activists persist in commending compulsory licenses in the hope that some developing countries will have the political fortitude and determination to issue compulsory licenses.

As previously discussed, TRIPS-compliant compulsory licenses are a relatively limited public policy tool. They will work well, for a while, for pre-1995 first generation HIV/AIDS medicines where a process-patent-only country is legally producing generic medicines. In these circumstances, a country issuing a compulsory license might be able to immediately import significant quantities of medicine. However, for second generation, post-1995 HIV/AIDS medicines and for medicines produced under a compulsory license issued in another country (and thus subject to “predominantly for domestic use” rules), a local compulsory license will be relatively unavailing unless the country has some significant pharmaceutical capacity.

Of course, a few African countries do have this capacity, especially South Africa, and it already has a major generic producer, Aspen. And other African countries can presumably develop some pharmaceutical capacity, if not to manufacture therapeutic base ingredients then at least to manufacture/assemble finished products. In this context, it is important to note that local production is not desirable just from an economic development point of view, though this should be sufficient given the structural HIV prevention benefits of poverty reduction, it is also important in terms of sustainability of supply. For these reasons, a bulk procurement policy strategy within the Global Fund should not be read as precluding reimbursement for generics produced locally under a compulsory license. Skeptics of local production are right to point out that in some instances delays in developing local pharmaceutical capacity would be significant and that there are capital and human capacity barriers that are problematic. South Africa, however, has previously had a relatively robust pharmaceutical industry that is being gradually dismantled in the post-TRIPS era;<sup>193</sup> this industry could conceivably be rejuvenated relatively quickly.

Despite some guarded optimism about compulsory licenses, it is clear that TRIPS imposes barriers which must be addressed, even though many African countries do not have patents on HIV/AIDS medicines. First and foremost, the “predominantly for domestic use” rule must be modified to permit export/import to developing and highly HIV-impacted countries. (Since many African countries have no pharmaceutical capacity whatsoever, the compulsory license regime is relatively meaningless if it requires local production.) This could be accomplished via a clarification in TRIPS to the effect: “In response to a public health need in a developing or highly HIV-impacted country, (1) medicines produced under a compulsory license in one country may be exported to such country or countries regardless of Article 31f and (2) medicines may be produced as an Article 30 exception for export to (a) countries that have issued their own compulsory license for such medicine or (b) to countries where no valid patent is on file.” An even broader reform would be one that abandons the pretense that a uniform international intellectual property regime is desirable and that instead recognizes the legitimate

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<sup>193</sup> Once Big Pharma did not have to “work the patent” locally via local production, it has started to dismantle smaller plants worldwide including 50 facilities in South Africa.

differences between developing and developed countries at least with respect to medicines essential to treat the pandemic diseases of the South. Unfortunately, such a roll-back of TRIPS is extremely unlikely.

In any event, no desirable modification of the compulsory license regime is likely to be accomplished if due deference is not given to the avoidance of product/price competition back in developed countries. Pharmaceutical companies and First World trade representatives would at a minimum demand assurances that compulsory license liberalization and limited exceptions for export would be limited to medicines supplied to developing and heavily-impacted countries and that there would be explicit barriers against gray and black market competition in developed countries. This assurance could result from clarifications/concessions on the parallel importation/exhaustion of rights rules in Article 6 as discussed further below.

### Demanding Parallel Importation

The future of parallel importation looks relatively dim to me, especially to the extent that voluntary licenses and compulsory licenses are pursued. At the very least pharmaceutical companies and First World trade representatives are going to seek protection from parallel importation of (1) price-discounted or concessionary drugs, (2) low-priced drugs produced under voluntary licenses granted to developing countries re HIV/AIDS and other pandemic diseases, and (3) low-priced drugs produced under compulsory licenses or as limited exceptions for export. Although Big Pharma as phrased its concerns historically in terms of parallel importation back into first world markets, this concern seems remote given existing legal rules in the U.S. and the E.U. outlawing international exhaustion (even though there is some tolerance for parallel importation within the EU). I suspect that the industry's true concern is in relation to middle-income countries where Pharma hopes to expand its future markets as purchasing power increases.

Activists started urging parallel importation when there were unconscionable price disparities in different markets and when certain medicines were more costly in some developing countries than they were in some First World countries. Tolerance of exhaustion of rights under Article 6 of TRIPS encouraged activists to demand that countries and consumers be able to comparison shop for patented medicines wherever they were sold most cheaply.

However, activists have recently succeeded in forcing partial price discounts for certain HIV/AIDS medicines and in addition licensing schemes may become more widely used. In this new context, to continue to demand universal rights of parallel importation risks preempting these other gains. The pharmaceutical industry and their governmental proxies in developed countries are simply not going to tolerate grey market importation of cheaper medicines into lucrative middle-income markets. At the very least, public health TRIPS reform may require a clarification or agreement tightening parallel importation rules vis a vis importation back to developed and middle-income countries even if it continues to permit parallel importation into developing countries.

### Demanding Public Health Limited Exceptions

Article 30 is a basically incoherent compromise between the need for some limited exceptions to TRIPS and the need for such exceptions to be TRIPS compliant. What this compromise means in fact is that decision-makers have incredible discretion to interpret the existing language in a way that permits the kinds of public health exceptions discussed above or to interpret the language to require relatively stringent adherence to the interests of patent holders. How this discretion gets exercised is one of the great debates of TRIPS jurisprudence. Clearly, who the decision-makers are and their social allegiances make a difference. Similarly, it is clear that decision-makers are influenced by social and political movements. It is customary to think

that tighter language limit discretion, but it does so imperfectly. Even plain language is rarely clear to a determined contrarian decision-maker. Nonetheless, my suspicion is that we would be better off demanding limited but clear public health exceptions under Article 30. One such exception, previously discussed, would create a limited exception to Article 31f permitting bypass of the primarily-for-domestic-use rule of and thus greatly expanding production and export of medicines produced under a compulsory license. A second exception, even broader, would permit production and export of essential AIDS medicines in response to a public health need in an importing country that has no patent and no or little productive capacity or to satisfy a compulsory license issued in a country with no or limited productive capacity.

### *The Outline of a Multinational Corporate Complicity Campaign*

Although the pharmaceutical industry has been and continues to be an appropriate target for treatment activist campaigns, it should not be the only corporate sector targeted; multinational corporations in many other industries have played a horrendous role in creating the socio/economic conditions for the pandemic and in neglecting their obligations to their workforce. Because of activist pressure and union activity, some MNCs are beginning to acknowledge the scope of the pandemic and plan minimal face-saving responses that protect limited segments of their skilled workforce. Moreover, some employer associations are drafting employment practice policy statements encouraging “corporate responsibility” in the age of HIV/AIDS, particularly in the area of awareness/prevention.<sup>194</sup> In general, these policies are weak in scope, particularly with respect to treatment of employees who are living with HIV. As a rule, MNC employers continue to practice discrimination against employees with HIV, to deny HIV medical care insurance or treatment, and to avoid wage continuation policies for their employees.<sup>195</sup> Thus, one of the emerging strategies for treatment activists is to expand the concept of MNC obligations beyond the liberal idea of “corporate responsibility” to the more accurate battle cry of “corporate complicity.”

Although a corporate complicity campaign might eventually spread to smaller employers, a multinational complicity campaign should initially be directed at large-scale employers in Africa, particularly those with foreign (U.S. and European) ownership. In this regard, the extractive industry, for example AngloGold, a subsidiary of Anglo American, is a particularly attractive target, especially given its recent decision to offer ARV therapy to office and management staff only, mostly white, but not to frontline miners, mostly Black.<sup>196</sup> These racist treatment plans must be exposed and countered with demands for universal treatment of all workers and their families. A variation of a corporate treatment campaign relates to whether the employer is providing for HIV/AIDS treatment to both its immediate *and* extended workforce. In this regard, Coca Cola, Africa’s largest direct and indirect employer, might be a desirable target given its decision to provide treatment for its 1500 direct corporate employees, again often white,

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<sup>194</sup> Global business Council on HIV/AIDS, [www.businessfightsadis.org](http://www.businessfightsadis.org) (12/6/01); Report of the Findings of the Corporate Council on Africa’s Task Force on HIV/AIDS (Oct. 12, 2001); see CDC – Global AIDS Program Technical Strategies – Private-Public Partnerships, [http://www.cdc.gov/nchstp/od/strategies/2\\_6\\_private\\_public.htm](http://www.cdc.gov/nchstp/od/strategies/2_6_private_public.htm) ((10/23/01). The International Labour Organization, now affiliated with UNAIDS, has also issued a Code of Practice on HIV/AIDS and the World of Work, <http://www.ilo.org/public/english/bureau/inf/pr/2001/24.htm> (12/05/01).

<sup>195</sup> There are a few exceptions. In Botswana, the diamond mining company Deswana is planning to provide anti-retroviral therapy to employees and family members. Deswana will cover 90% of the cost of ARVs. Similarly, Daimler Chrysler, the largest private investor in South Africa is also reported to have pledged anti-AIDS drugs to its South African employees and families.

<sup>196</sup> *Anglo American Will Not Provide Majority of South African Workers with Antiretroviral Drugs*, Kaiser Daily HIV/AIDS Summary (10/9/01). Anglo had previously made an announced on May 8, 2001 that it would provide cheap anti-AIDS drug to its employees.

but not to its 100,000 indirect employees, most black, who are formally employed by Coke's affiliated bottlers.<sup>197</sup>

Because the extractive industry and other migrant industries in Africa, i.e., plantations, final assembly plants, large infrastructure projects, have played a crucial role in exacerbating the AIDS crisis through their single-sex housing practices, another goal of a corporate complicity campaign would be a demand for more family/community friendly housing schemes. Yet another piece might relate to corporate HIV/AIDS prevention, testing/counseling, and treatment clinics at worksites (all within a culture of non-discrimination). A key part of any multinational corporate complicity campaign is to characterize comprehensive prevention and treatment programs as a form of restitution/reparations for past histories of colonial and neo-colonial wealth extraction and wealth transfer.

The clearest rationale for a corporate responsibility/complicity campaign is that multinational corporations are the architects of globalization, the WTO/World Bank/IMF troika, US trade policy, and the neo-liberal politics that are disseminating African economies and intensifying the AIDS pandemic. Bringing MNCs out of the background, into the foreground where they belong, is important to mounting an effective treatment campaign. Multinational corporations will have sophisticated spin for their quarter-measures, but an inspired and vigorous campaign can keep them in the spotlight.

A second justification for an MNC corporate complicity campaign, beyond their direct complicity in creating the conditions for the pandemic, is that large-scale employers have the means, the organization, and the infrastructure to deliver AIDS treatment to a large segment of the population. Once problems of stigma and discrimination are addressed, worksites might be ideal settings for testing, education, and medical care for non-migratory workers and their families. In addition, activists should not underestimate the importance of extending the lives of "economically" productive workers. In South Africa, working family members often support an entire network of relatives in two extended families, including AIDS orphans. For example, a rural teacher visiting my family this summer supports himself his wife and his two children, but in addition he supports 16 other family members including surviving members of two breadwinners who died of AIDS last year. It is also important to remember that these workers are parents too, and their survival is critical to the nurture and support of their own children.

Third, a campaign against corporations can create an even stronger alliance between trade unions and treatment activists. COSATU has become an important member of the treatment campaign in South Africa and is, of course, a supporter of TAC's lawsuit against the government on MTCT. COSATU has played an increasingly supportive role in criticizing government's apathy. If activists construct a campaign that links demands for company-specific AIDS treatment with broader demands for corporate contributions to universal treatment options, then activists will have succeeded in further politicizing and connecting with a very important constituency. In this context, it is also appropriate to mention that there is growing dissent in the ANC about Mbeki's AIDS policy and there are many ANC comrades who are just as treatment about treatment as activists are - it's their family members and loved ones who are dying.

The final advantage of a corporate campaign is that it can be launched in the belly of the beast. The U.S. is home-sweet-home to the inner-circle of corporate hegemony. While Southern allies push their governments and rally against local multinational subsidiaries, treatment activists in the U.S. can demonstrate at world headquarters. While Jeffrey Sachs and other corporate apologists are trying to keep corporations, including pharmaceuticals, out of the spotlight, Activists can say that the MNC emperors are wearing stolen loot and spreading the plague.

Although there are many advantages in a multinational corporate complicity campaign, there are dangers as well. One danger inherent in the corporate responsibility/private sector workforce/medical aid scheme plan is that it constitutes a form of privatization. The scope of the

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<sup>197</sup> Donald G. McNeil Jr., *Coca-Cola Join AIDS Fight in Africa*, New York Times (June 21, 2001).

pandemic in South Africa and in Africa in general cries forth for massive governmental and regional responses. There is a perverse collusion of interest in saving the lives of the "economically" productive members of the formal economy and letting the rest die. Certainly corporate interests would prefer to pay for narrowly tailored, company-specific programs rather than contribute through taxes and otherwise to a more universal public response. Similarly, COSATU and labor elites, despite having done many positive things in the anti-Apartheid struggle and in the cause of labor reform, have been justly accused of having a trade-union focus on their current membership at the expense of more vigorous solidarity with their un- and under-employed brothers and sisters. Finally, some of the more cynical forces in the South African government seem to be focused on saving their own ranks and economically productive workers and letting the desperately poor die (at least by waiting until the big bucks arrive or until a vaccine or microbicide is developed). In other words, one of the dangers of a corporate, privatization scheme is that treatment would stop at "private sector borders" leaving the vast majority of people living with HIV/AIDS on the outside. By satisfying and treating the more educated, more politically active, and better organized private sector, there can be a significant loss of solidarity with rural, peri-urban, and informal sector folks.

*Contours of a Multinational Corporate Complicity Campaign<sup>198</sup>*

As a result of these multiple forms of corporate misfeasance, a multinational corporate complicity campaign could demand that:

- MNCs pay their full share of tax commitments that are the source of funds for public sector services. (MNC have a long history of avoiding taxes, demanding special tax concessions, having dubious accounting practices to avoid their tax responsibilities.)
- MNCs provide resources to the Global Fund, which will be used to meet the prevention, care, and treatment needs of people with HIV/AIDS and other infectious diseases.
- MNCs in no way use contributions to the Global Fund to decrease their tax responsibilities to governments. Such contributions must be entirely new funds, and not a shifting of tax responsibilities.
- Where MNCs directly or indirectly provide health care to their employees, they must provide full HIV care including anti-retrovirals to these employees and their family and household members.
- Where MNCs currently do not directly or indirectly provide health care to their employees and their family and household members for full HIV care including anti-retrovirals, they should promptly do so.
- MNCs provide anti-retroviral therapy to prevent mother-to-child transmission for employees and their family or household members and they also provide post-rape anti-retroviral therapy to employees and their family or household members.
- Where MNCs indirectly provide for health care through medical aids schemes or otherwise, the coverage should not require onerous co-payments or impose benefit limitations that unfairly shift costs of HIV care to the employee.
- MNCs must ensure that outsourced or franchised contracts are conditioned on and resourced sufficiently to provide equivalent HIV care to the outsourced workforce. (MNCs often outsource activities, or have 'franchises' in order to avoid responsibilities of providing full benefits to their workers.)
- Where feasible, MNCs should extend prevention and treatment coverage to surrounding communities.
- MNCs support voluntary and confidential HIV testing with clear statements of non-discrimination.
- When MNC directly or indirectly provide health services to employees and family and household members with HIV/AIDS, MNCs provide the option of care that is not linked to the employer to preserve anonymity and to prevent discrimination and employer retribution.

<sup>198</sup> This is a tentative list of demands discussed by Health GAP during the fall of 2001.

- MNCs provide full protective measures to prevent HIV transmission in the workplace, where that is a possibility.
- MNCs provide full access to male and female condoms and other emerging protections against transmission to their employees and their family and household members.
- MNCs provide or permit full workplace access to NGOs for HIV education and risk reduction messages.
- MNCs end employment related distortions that have led to single-sex housing and company towns.
- MNCs must continue HIV care to employees, families and household members who are no longer able to work.
- MNCs must provide wage continuation so people with HIV/AIDS who can no longer work are not destitute.

*Other Strategic Issues in the African AIDS Access to Treatment Campaign*

As the recent flurry of press releases has demonstrated, there is much to celebrate in the African AIDS access to treatment campaign. First, activists around the world mobilized in support of TAC's call for a Global Day of Action on March 5, 2001, and ultimately the drug company lawsuit against the South African Government was dropped in April of 2001. Second, in June of 2001, the U.S. government was forced to drop its WTO complaint against Brazil, again because of international pressure. Third, the UN convened its first General Assembly on AIDS in June of 2001 and issued a dramatic proclamation on the necessity of a heightened response to the AIDS pandemic; at the same time, Kofi Annan announced the formation of the Global Fund which has raised more than \$1.6 billion in less than a year. Fourth, treatment advocates have won significant concessions/clarification concerning the TRIPS Agreement at Doha in November of 2001 such that the legal route to affordable medicines is clearer than it has ever been before. Fifth, there has been an unprecedented amount of news and editorial coverage in major media sources, much of it outlining pricing/profit excesses in the pharmaceutical industry and pressing demands for major price concessions and dramatically increased aid from the developed countries for the purchase of lower cost medicines; as a result, the industry has initiated a new round of unilateral price reductions that are more than matched by even steeper generic price reductions. Finally, in the fall of 2001, TAC filed a lawsuit against the South African government seeking a MTCT prevention program in the public sector and won an important legal victory in December.

It is important to celebrate these significant victories but also to analyze them as activists plan their continuing campaign. It is particularly important to figure out how to continue pressure on the drug industry, the U.S. Trade Representative, and the architecture of TRIPS as the industry tries to produce one favorable news story after another with tactical offers that ALWAYS promise more than they deliver. This will be particularly important in organizing an activist campaign, where the question will be "which price concessions are real," "what are the real marginal costs of production," "what conditions concerning security of distribution channels, if any, are reasonable," and most especially "must we continue to press for changes in the intellectual property regime - multilateral (TRIPS), regional (FTAA), and bilateral - to permit production of lowest cost, high quality generics?" With respect to this last question, activists must seriously consider the propriety of proposals for licensing HIV/AIDS medicines to WHO or other international bodies who would tender bids for extremely large and efficient generic manufacturers, who might in turn achieve significant economies of scale but raise prices because of a lack of competition.<sup>199</sup> An alternative proposal would encourage local and/or regional production in countries with some pharmaceutical capacity, thereby stimulating development, broader-based economies, and increased self-reliance.

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<sup>199</sup> This is one of the proposals put forth by OXFAM.

As the movement for access to HIV/AIDS medicines grows, it becomes both more powerful and more diffuse. Certain ideological battles become more significant, e.g., corporate malfeasance/anti-globalization vs. governmental aid/liberalism, and significant tactical problems arise as well, e.g., civil disobedience, mass rallies, teach-ins. Finally, there are difficult problems of coordination and community mobilization. At present, the movement relies on the tactical zeal of HealthGAP/ACT-UP, the political/moral/mass leadership of TAC (building on a base of anti-apartheid activists), the technical expertise of James Love, Health GAP and others concerning the intricacies of TRIPS and other intellectual property regimes, and the energy/good will of communities of faith, campus activists, anti-globalization activists, and now labor elites. However, the movement is not even close to being mass-based, except to some extent in South Africa. The activism of a relatively small cadre burns bright, but it also risks burning out because of the vicarious emotional costs of dealing with this crisis indefinitely and because of the increasingly sophisticated counter-campaign that is and will continue to be launched by industry and governmental opponents.

TAC, Health GAP, and other activist organizations, in addition to seeking to give voice to people living with HIV, seek to expose the industry's abusive pricing. They do so first by documenting the dramatic variations in pricing in different countries and by documenting the much cheaper generic medicines available in India, Thailand, and Brazil. They do so secondly by demanding that the industry reveal its heretofore closely guarded trade secrets concerning the actual marginal costs of manufacturing HIV/AIDS medicines. (It is unclear whether the industry will actually disclose costs, as that might provoke consumer backlash in the U.S., or whether it will use various legal strategies of delay and appeal to avoid the issue.) They do so thirdly by exposing the industry's efforts to crush generic competitors and to solidify its intellectual property rights in Congress, with the U.S. Trade Rep, and at other international forums including the WTO. Although the industry lost certain ground at Doha, the U.S. Trade Rep can be expected to continue to seek TRIPS plus intellectual property protections in bilateral and regional trade agreements such as FTAA, especially given the imminent passage of fast-track trade authority.

As various activists have noted, an abundance of press has risks as well as rewards. For example, many of the stories offer extraordinarily invidious and racist images of people in Africa to a U.S. public that is culturally primed to a racist reaction. Second, Big Pharm's excuses/disinformation are nearly always reported in the mass media with little real criticism, especially in the shorter articles that most people are likely to read. Third, the scope and complexity of the HIV/AIDS pandemic can be demoralizing and/or provoke empathy exhaustion. Finally, media saturation suggests subtly that something is being done or that it will be done. It lulls people into a false sense of progress.

The pharmaceutical industry has launched its third major media campaign about its alleged price reduction program(s). The first series of announcements concerned limited trials designed to test the technical feasibility of implementing complex drug treatment and monitoring regimes in African countries with poor infrastructures. The second series of announcements was in the run-up to the XIII International AIDS Conference in Durban where the industry tricked UNAIDS into being a co-sponsor of its country-by-country, drug-by-drug negotiation scheme. Now, as an alleged result of "learning from experience", the industry, starting with Merck and Bristol-Myers, has announced a new, deeper, and broader price reduction program. It is important to note as well that Pfizer seized the high ground earlier on World AIDS Day by its partial fluconazole donation agreement with South Africa. Boehringer Ingelheim seized even higher ground offer last year to provide nevirapine free of charge to prevent mother-to-child transmission.

In this context, it will be important to emphasize that the drug companies have responded, slowly, incrementally, and on a piece-meal basis, only because of Africa AIDS activism. To suggest that the companies are "learning" is sinfully naive. That is not to say that there aren't

voices supporting accessible medicines campaigns within the companies and within the industry, but it is to say that those voices would not be heard were it not for the pressure of activists and the bad press the industry has been receiving. Thus, when activists celebrate limited victories, they should celebrate them primarily as victories of activism and as proof that pressure counts.

However, the industry is going to become increasingly sophisticated in its counter-publicity campaign, in its counter-insurgency in the accessible medicines movement, and in its vituperative, indignant response to activists "who will never be satisfied." In other words, activists have gotten a relatively free ride in terms of negative stereotyping because the moral weight of their cause is so compelling. But, as the industry increasingly lauds its responsiveness, and as the real difficulties of implementation, capacity building, corruption, and drug resistance rise, the industry will try to paint activists into a smaller and smaller corner as fringe zealots who don't know when they've got a good deal.

Liberal academics, including Jeffrey Sachs and Amir Attaran of Harvard's Center for International Development, have launched a counter-campaign focusing on governmental aid and excusing the pharmaceutical industry and other multinational corporations. On several occasions, CID spokespersons have gone out of their way to say the "industry is on board," that AIDS anti-pharmaceutical activism is anti-capitalism in disguise, and that all that remains is a modest, doable money campaign to get \$1 billion from the U.S. government and like amounts from the donor countries of Europe. Moreover, Sachs et al. point to the most recent corporate press campaign as proof that they were right and that the industry really is on board. However, the two questions to keep front and foremost in the activist campaign are: (1)"Is the industry really on board when it continues to offer fractional solutions to a plague?" and (2)"Are the forces of neo-liberal globalization really on board when they have done so much to intensify and perpetuate the pandemic through false promises of trickle-down development and poverty alleviation?"

All of which brings me to a series of thoughts about the ongoing activist campaign. For me, three major concerns dominate: (1) worldwide, mass scale production to achieve lowest costs vs. local development of generic pharmaceutical capacity; (2) strategic interpretation of loopholes, ambiguities, and compromises in the TRIPS Agreement to foster compulsory licensing, limited exceptions, and parallel importation vs. advocacy for major changes in or abrogation of the international intellectual property regime; and (3) targeted governmental aid on a more massive scale vs. massive debt relief freeing \$14.5 billion dollars in annual debt payments in Africa tied to a governmental commitment to anti-AIDS work. Of course, there are even larger concerns about reform vs. elimination of the World Bank, International Monetary Fund, and World Trade Organization and about building a movement for economic democracy and true wealth redistribution and equitable development. But as long as activists focus their campaign on access to medicines, these are likely to be background rather than foreground concerns.

Answers to these questions have important impact on future activism. They impact whether activists continue to demand relaxation of the patent regime as well as deeper and deeper price cuts and increased governmental aid and loan forgiveness. They affect activist street theater and demonstrations, community education activities, and collaborations with other activists. In the legal arena too, they affect choices of tactics and selection of legal campaigns some of which are outlined below:

*Fighting Back in the First World: An Outline of a Governmental/Global Institutions Campaign*

- Pressure the U.S. government, G-7, World Bank, International Monetary Fund, and other international lenders to eliminate or greatly reduce African debt to free money for social spending, particularly health care.
- Pressure the U.S. government, G-7, World Bank, International Monetary Fund, and other international lenders to dramatically increase foreign monetary and technical assistance targeted towards: (1) HIV

prevention and treatment, (2) capacity building in the public health sectors, and (3) democratic economic development. This assistance should be in the form of aid, not loans. This assistance should be collaborative rather than highly conditional.

- Pressure the U.S. and other developed countries to fully fund the Global Fund, to support treatment as well as prevention, and to promote Southern participation, transparency, and accountability in decision-making.
- Pressure the U.S. government, G-7, World Bank, International Monetary Fund, World Trade Organization, other international structures to dramatically reverse neo-liberal economic policies that distort local economies exclusively toward export/import markets, that depopulate rural economies, and that increase unemployment, economic inequality, and the feminization of poverty.
- Pressure the U.S. government, G-7, World Bank, International Monetary Fund, World Trade Organization, other international structures to reverse international currency exchange policies that encourage capital outflows from developing countries and irrational currency devaluations.
- Pressure the U.S. government, G-7, World Trade Organization, other international structures to revise international intellectual property regimes, e.g., TRIPS, that protect profits at the expense of millions of lives. Possibilities include:
  - to reassign HIV/AIDS vaccine and drug research and eventual manufacture/ distribution of HIV/AIDS medicines to the World Health Organization and other international bodies to take advantage of economies of scale;
  - to eliminate intellectual property regimes for life-saving medications such as HIV anti-retrovirals, especially since most of these medications were developed at public expense;
  - to authorize increased production of generic medication through compulsory licensing that provide only modest royalties to patent holders; this option helps to build local capacity and local economies in developing countries;
  - to authorize limited exception permitting production for export to countries with compulsory licenses or without patents that lack capacity to manufacture medicines on their own;
  - to promote parallel importation of cheaper patented medicines from other countries;
  - to expand the doctrine of abuse of patents to include pricing schemes that price developing countries out of the pharmaceutical market;
  - to dramatically shorten the length of patents in pharmaceuticals from 20 years and to eliminate extended patents for minor modifications of existing medicines, e.g., dosages, combinations, pill forms;
  - to control prices of HIV/AIDS medications through national and international fair pricing regimes that account for public expenditure, research and development costs, marginal costs of production, and modest (not 20%) rates of return.
- Pressure the U.S. and international legal systems to recognize the primacy of human rights, particularly progressive rights to health care and poverty reduction, over property rights, particularly intellectual property rights.
- Pressure the U.S. government to stop using threats of trade sanctions to coerce African countries not to use TRIPS-compliant parallel importation, limited exceptions, and compulsory licensing mechanisms to respond to the HIV/AIDS crisis. Support legislation that would make such threats illegal.
- Support upcoming legislation providing for sustainable, equitable, and democratic development. More generally, support greatly increased foreign aid to developing countries.
- Support and undertake litigation aimed at abuse of patents by U.S. pharmaceuticals and pressure the U.S. government to exercise rights it currently has to reassert control over or to impose pricing and distribution conditions on HIV/AIDS medications developed at public expense.

## APPENDIX A

<b>Articles in TRIPS most relevant to access to pharmaceuticals</b> (Note: a number of articles contain further specific conditions, exceptions and exemptions which are spelled out in TRIPS or other referenced agreements.)	
<b>Nondiscrimination</b> (Articles 3, 4, and 27)	<i>"National Treatment...</i> Each Member shall accord to the nationals of other Members treatment no less favourable than that it accords to its own nationals with regard to the protection of intellectual property..." <i>"Most-Favoured-Nation Treatment...</i> With regard to the protection of intellectual property, any advantage, favour, privilege or immunity granted by a Member to the nationals of any other country shall be accorded immediately and unconditionally to the nationals of all other Members..." "[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."
<b>Parallel importation ("exhaustion of patent rights")</b> (Article 6)	<i>"Exhaustion..."</i> For the purposes of dispute settlement under this Agreement, subject to the provisions of Articles 3 [National Treatment] and 4 [Most-Favoured-Nation Treatment], nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights."
<b>Objectives of TRIPS</b> (Article 7)	<i>"Objectives..."</i> The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations."
<b>Protection of public health</b> (Article 8)	<i>"Principles..."</i> Members may, in formulating or amending 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."
<b>Process and product patents</b> (Article 27)	<i>"Patentable Subject Matter..."</i> patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application."
<b>Subject matter which may be excluded from patentability</b> (Article 27)	<i>"Patentable Subject Matter..."</i> Members may exclude from patentability inventions...necessary to protect <i>ordre public</i> or morality, including to protect human, animal or plant life or health..." "Members may also exclude from patentability: (a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals; (b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes."
<b>Rights Conferred</b> (Article 28)	<i>"Rights Conferred..."</i> 1. A patent shall confer on its owner the following exclusive rights: (a) where the subject matter of a patent is a product, to prevent third parties not having the owner's consent from the acts of: making, using, offering for sale, selling, or importing for these purposes that product; (b) where the subject matter of a patent is a process, to prevent third parties not having the owner's consent from the act of using the process, and from the acts of: using, offering for sale, selling, or importing for these purposes at least the product obtained directly by that process. 2. Patent owners shall also have the right to assign, or transfer by succession, the patent and to conclude licensing contracts."

### Articles in TRIPS most relevant to access to pharmaceuticals

(Note: a number of articles contain further specific conditions, exceptions and exemptions which are spelled out in TRIPS or other referenced agreements.)

<p><b>Limited exceptions, including "Bolar" provisions</b> (Article 30)</p>	<p><i>"Exceptions to Rights Conferred...Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties."</i></p>
<p><b>Compulsory licensing</b> (Article 31)</p>	<p><i>"Other Use Without Authorization of the Right Holder...Where the law of a Member allows for other use of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected.</i></p> <ul style="list-style-type: none"> <li>(a) authorization ... shall be considered on its individual merits;</li> <li>(b) such use may only be permitted if, prior to such use, the proposed user has made effort to obtain authorization from the right holder on reasonable commercial terms and conditions and that such effort have not been successful with a reasonable period of time. This required may be waived ... in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial [governmental] use.... [Notice is required.]</li> <li>(c) the scope and duration of such use shall be limited to the purpose for which it was authorized ...;</li> <li>(d) such use shall be non-exclusive;</li> <li>(e) such use shall be non-assignable ...;</li> <li>(f) any such use shall be authorized predominantly for the supply of the domestic market ...;</li> <li>(g) authorization for such use shall be liable, subject to adequate protection of the legitimate interests of the persons so authorized, to be terminated if and when the circumstances which led to it cease to exist and are unlikely to recur [with provisions for review] ...;</li> <li>(h) the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization;</li> <li>(i) the legal validity of any decision relating to the authorization of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;</li> <li>(j) any decision relating to the remuneration provided in respect of such use shall be subject to judicial review or other independent review ...;</li> <li>(k) Members are not obligated to apply ... subparagraphs (b) and (f) where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive [and may take account of anti-competitive practices in setting compensation] ....</li> </ul>
<p><b>20-year minimum term of protection</b> (Article 33)</p>	<p><i>"Term of Protection...The term of protection available shall not end before the expiration of a period of twenty years counted from the filing date."</i></p>
<p><b>Data protection and Exclusivity</b> (Article 39)</p>	<p><i>"Protection of undisclosed information...In the course of ensuring effective protection against unfair competition...Members shall protect undisclosed information...and data submitted to governments or governmental agencies..."</i></p>
<p><b>Transitional Periods</b> (Articles 65 and 66)</p>	<p>TRIPS provides a period of transition during which countries are required to conform their national legislation and practices to its requirement. The latest dates for WTO Members were/are: 1996 for developed countries; January 1, 2000, for developing countries (as a general rule); January 1, 2005, for developing countries who had not introduced patents before joining the</p>

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	WTO; and January 1, 2006, for least-developed countries. TRIPS specifically acknowledges the economic, financial, administrative and technological constraints of the least-developed countries and therefore provides for possible extension of the transitional period.
<b>Transfer of technology and technical cooperation</b> (Articles 66 and 67)	"Developed country Members shall provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer to least-developed country Members in order to enable them to create a sound and viable technological base...[and] shall provide, on request and on mutually agreed terms and conditions, technical and financial cooperation in favour of developing and least-developed country Members."
<b>Review</b> (Article 71:1)	"The Council for TRIPS shall review the implementation of this Agreement after the expiration of the transitional period referred to in paragraph 2 of Article 65. The Council shall, having regard to the experience gained in its implementation, review it two years after that date, and at identical intervals thereafter. The Council may also undertake reviews in the light of any relevant new developments which might warrant modification or amendment of this Agreement."

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