from *The Subcontinental*, Issue 2:1 -- Spring 2004
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Of Patents and Patients:
Giving AIDS Patients the Right to Treatment

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Little Miguel was one of my first AIDS patients in New York City. He was only 11 months old when I met him. His mother had just learned of her own HIV positive status and had brought her two children to me for testing. Her older daughter, Helena, was almost 6 years old. She was a savvy, fresh-faced inner city kid -- all attitude and style. She kicked and screamed throughout the blood test. “You think I got AIDS or something?” she said. “You crazy.” Her brother Miguel said nothing. He had never spoken a word, couldn't sit without support, and would only eat food that was pureed. His mouth was raw with thrush[1] and his collar was stained with pus from an ear infection that refused to heal. His mother couldn't stop crying. She knew enough to know what ailed him. Helena tested negative, but Miguel was infected. His T-cell count was lower than any I had ever come across. I told his mother that it was a miracle he was alive. We could give him supplemental nutrition, treat his thrush, and try some antibiotics to prevent pneumonia, but the end was perilously close. Three days later, the first research trial of cocktail AIDS treatment for children began. I called Miguel's mother and told her that there could be hope for him. Although the treatments were highly experimental, we decided it was better to try than do nothing. We started Miguel on a combination of three HIV antiretroviral medicines and waited for results. Within three months Miguel was walking and talking.

Almost eight years have passed since then, and Miguel and I have both moved on. He just celebrated his ninth birthday (he came to show me his new CD walkman), and I now spend much of my time working with HIV-infected children in Mombasa, Kenya. In many ways, my work in Africa reminds me of the early days of the AIDS epidemic in New York. There are the same desperately sick children, the same fear and sadness, and the same sense of inevitability. But, of course, New York and Kenya differ in one criti-

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cal aspect. Until recently, there was no public access to antiretroviral drugs in the developing world. The past year has seen a tremendous fall in the cost of HIV therapy, due in large part to the role played by international activist organizations and generic drug makers in India. Although the legal battle to bring generic HIV drugs to the market has been long and bitter, the ultimate defeat of the pharmaceutical industry represents the tides of change in the fight to expand access to essential medications.

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In the wake of its 2001 summit meeting in Qatar, the World Trade Organization announced that the set of WTO rules covering patents on drugs -- the Agreement on Trade-Related Intellectual Property Rights (TRIPS) -- "can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all."[2] The United States and Switzerland, which are home to the world's largest pharmaceutical companies, had actively opposed the wording of the statement, proposing instead that WTO Member states be permitted only to "use to the full" the existing provisions in the TRIPS Agreement. But in the end, faced with the threat of a boycott from a united Third World, they backed down. This outcome was the direct result of the tremendous publicity given to the defeat of Big Pharma in its three-year lawsuit against South Africa. Initiated by a mega conglomerate of 39 pharmaceutical companies, the legal action argued that a 1997 Act passed by the South African government to override drug patents was unconstitutional and violated the rights of drug manufacturers. The South African legislation had taken advantage of existing provisions in the WTO agreement that allowed states to circumvent patent regulations. Although these provisions were on the books, they had rarely been invoked by developing nations due to strong pressure from pharmaceutical companies with the backing of Europe and the United States. In particular, prior to 1997, no country in the Global South had ever issued a "compulsory license" -- a permit to allow local manufacturers to bypass a patent and produce generic versions of a drug in the event of an overwhelming public health need. The AIDS crisis finally compelled South Africa to take this step. Soon after the pharmaceuticals dropped their action against South Africa, the U.S. Trade Representative to the WTO withdrew an official complaint against Brazil, whose pharmaceutical industry had already started producing generic antiretrovirals for the domestic market.

For maverick business mogul Dr. Yusuf Hamied, the decision to manufacture generic antiretrovirals was a humanitarian response to a global

crisis. Dr. Hamied is the chairman of Cipla, India's third largest pharmaceutical company. Although India is a signatory to the TRIPS agreement since 1995, the 1970 India Patents Act prohibits the patenting of any substance which can be used as a food, medicine, or drug (only processes can be patented). In any case, India has until 2005 to fully implement the TRIPS agreement. As a result of this, at present, India permits its drug manufacturers to make any licensed medication provided they do so using a chemical process which is different from that of the patent holder. Cipla had been making generic versions of antiretrovirals since 1993, but at a meeting of the European Union in Brussels in 2000, Dr. Hamied publicly offered to sell an AIDS drug cocktail at less than a tenth of the going commercial price. He even threw in a 5% licensing fee to patent holders (to date, none of them have accepted this royalty). Cipla's announcement stunned the world community and called into question the exorbitant prices of the multinational pharmaceuticals. Drug makers have always maintained that high drug prices and lengthy patents are necessary to recoup the tremendous costs of research and development of new drugs, estimated at 500 to 800 million dollars. But, ironically, many of the antiretroviral drugs were actually discovered by publicly funded researchers and tested in government supported clinical trials in Europe and the United States.

In the face of overwhelming negative publicity, a group of pharmaceutical companies have now established access programs for developing countries to purchase brand name antiretrovirals at reduced costs. This latest move however, is at best a reluctant one, and so the political battle over patents continues. In the latest development, U.S. agencies have expressed concern at the safety of generic drugs. They argue that generic "fixed dose combinations" (FDCs) such as Cipla's "Triomune" which contains three drugs in one tablet, are untested and might prove unsafe.[3] Yet Cipla's manufacturing facilities have been approved by international inspectors, and Triomune itself has received WHO pre-qualification for the treatment of HIV and AIDS. Moreover, the individual medicines in Triomune have long been taken in combination and have a proven record of clinical success. International AIDS activists have pointed out that one of the main reasons why these FDCs have not been developed before is because different companies hold the patents on the drugs they contain, and only a generic producer could combine them. At a dose of one tablet twice a day, Triomune is far more convenient than the majority of HIV drug regimens -- a factor which is highly likely to improve patient adherence and the long term success of treatment programs. Triomune and other generic FDCs have received the endorsement of the Global Fund to Fight AIDS Tuberculosis & Malaria, as well as international health bodies such as Médecins Sans Frontières and UNICEF. But in a recent turnaround of policy, former pharmaceutical chief Randall Tobias, who is

US Global AIDS Coordinator and directs the President's Emergency Plan for AIDS Relief (PEPFAR), has mandated that all US funded AIDS treatment programs purchase brand-name drugs instead of generics.

The Clinton Foundation recently announced that it had brokered a deal with Cipla to purchase FDCs for use in a group of African countries at the wholesale price of less than 140 dollars per patient per year. But in spite of these positive developments towards global access to HIV drugs, many obstacles to universal treatment still remain. The average annual health expenditure in Africa is under 10 dollars per person, and, even at the rock bottom cost of 140 dollars a patient, few countries can afford to buy drugs for their HIV-infected populations without international assistance. The Global Fund and the WHO's mandate to treat 3 million people by 2005 are woefully underfunded, and in many parts of the world, there are still tremendous educational and infrastructural barriers. While generic makers have slashed the cost of some drugs, the majority remain prohibitively expensive. This means that, for poor patients in the developing world, there is a very limited range of affordable therapies if the recommended first-line regimen fails. Treatment choices for children continue to lag behind those for adults. Only a handful of medications are made in easy to administer liquid form. In Mombasa today, it costs almost twice as much to treat a child with syrup medicines as it does to treat an adult with pills.

But for the first time in my years of work in Kenya, I feel a sense of public excitement and anticipation. Drug prices have fallen faster and further than anyone expected, and with the establishment of manufacturing facilities in other countries like China, Thailand, Indonesia and South Africa, prices are set to drop further. At the AIDS Research and Family Care Clinic which I established in Kenya's Coast Province General Hospital, we are now able to offer free treatment to almost 40 children with AIDS. It is the proverbial tip of an enormous iceberg, but for the parents and staff of the clinic, seeing these children improve is a miraculous feeling. There is a comment box in the clinic's waiting room, and on a recent visit to Kenya, I unlocked the box to read the sheaf of papers inside. There were no complaints of lengthy waits or unhelpful staff. No mothers who were bitter that their children had fared less well than others. Instead, all of them were expressions of hope and gratitude and love. Now that's a miracle!

1. Thrush is an opportunistic fungal infection of the mouth and other mucous membranes that is common among HIV patients.
2. The Doha Declaration is available from the WTO website - www.wto.org
3. Excerpted from Global Aids Coordinator Randall Tobias' testimony to the Foreign Operations Subcommittee, March 18, 2004.