

General Background

BigPharma Corp (BPC) is a major pharmaceutical TNC with headquarters located in the United Kingdom. Last year, after significant investments in R&D, BPC researchers received a patent from the European Patent Office for algoterine, considered a revolutionary new second line medication used in treating HIV/AIDS. The IP Department at BPC simultaneously filed patent applications in a number of countries, including the Sotowa Republic, a least developed country in sub-Saharan Africa with a population of 25 million. In January 2007, the application in Sotowa was approved by the country's patent office, for the statutory period of 20 years from the date of filing (two years ago).

Due to its rich mineral resources, Sotowa Republic generates a sizeable amount of income and has in the past few years enjoyed a relatively strong growth rate. Accession talks were successfully concluded permitting Sotowa Republic to join the World Trade Organization in 2002. Sotowa is also a member of the Arunga Economic Community (a regional intergovernmental organization and customs union made up of five least developed countries in the region), and is contemplating entering into a bilateral investment treaty (BIT) with the United Kingdom. Representatives of the African empowerment movement within Sotowa and some elements of civil society have voiced concern on the issue of entering into BIT negotiations with the UK, however. Sotowa has to date used a significant portion of its development assistance to build human capital. For instance, the country established a medical and pharmaceutical university ten years ago, which is relatively well respected and is attended by students from Sotowa and neighboring countries.

As with many sub-Saharan African countries, Sotowa Republic has a major health crisis with close to 20% of their population between 18 and 35 being HIV positive. Life expectancy has dropped significantly over the past decade to 47 years. The Sotowa Ministry of Health (SMH) has therefore, in addition to other measures (including fundraising for donations of ARVs from donor governments or cash to purchase them), prioritized access to affordable medicines as an important means to address this problem. After a recent review, the SMH decided to add algoterine to their list of essential medicines.

Founded by graduates of the national medical and pharmaceutical university, GeneRex Corp. (GR) is a local firm that has to date manufactured selected over-the-counter drugs for the Sotowa population. Its initial success has enabled it to invest in production capacity, and they are currently producing seven different over-the-counter (OTC) drugs. Most of the inputs are imported. GR is also a distributor in the region for a number of generic drugs made by a fast-growing Indian generic manufacturer, International Pharmaceutical Enterprise (IPE).

The Kingdom of Kando borders Sotowa Republic to the south, with which it enjoys good relations. Kando is a landlocked LDC. Its sole industry is to manufacture cheap garments for export that enjoy preferential tariff treatment in developed markets. Many of these manufacturers are Chinese and Indian, and have pulled out of Kando in recent years leaving behind empty factories and warehouses. Kando has to date never manufactured any medicines. Almost half of its workforce remains unemployed. While it harbors intentions of one day becoming a WTO member, it has not yet been able to conclude, let alone seriously start, accession talks. Kando is, however, also a member of the Arunga Economic Community.

The health crisis in Kando is even more serious than the one in Sotowa. The population relies on donations for a large proportion of their essential medicines. These medicaments are distributed either through aid agencies or through KandoPharmacies (KP), the only notable retailer of medicaments in the country. The majority of shares of KP are owned by GR. The Kando Ministry of Health (KMH)

also has recently included algoterine on their list of essential medicines. BPC has not applied for a patent in Kando.

Both Sotowa and Kando have laws which permit the issuance of a compulsory license upon the failure to agree on terms for the manufacture and sale of a pharmaceutical product that is the subject of a registered patent, with the requirement that the owner of the patent must receive fair payment therefore. Neither country has so far issued such a compulsory license, however. Both Sotowa and Kando laws permit the parallel importation of pharmaceutical products, a situation where a local producer may consider selling its cheaper products to richer countries, for example, South Africa or Thailand. Further, both Sotowa and Kando permit the issuance of government use licenses of pharmaceutical products. Neither the laws of Sotowa or Kando provide for clinical test data exclusivity, though owners may file claims under the respective unfair competition laws.

The guarantee of quality is an important issue. Even when medicines and other products get to infected people, they may not always be of good or adequate quality. Sometimes the best available medicine can have substantial side-effects, be toxic or can even be counterfeit. Exactly how regulatory authorities can guarantee quality or what methods and methodologies are appropriate in regulating medicines depends on a range of circumstances and case-by-case judgments about risks and benefits. Issues of quality include both the production of algoterine as well as proper storage and labeling techniques. Methods to insure proper quality must be discussed and can potentially include, among other options, government regulation, third party audits or direct regulation by either BPC or IPE. Issues with respect to the Sotowa or Kando government's ability to effectively regulate the domestic production and marketing of algoterine will also be relevant.

Executives at GR have succeeded in inviting a team of representatives from BPC to explore the possibility of negotiating a license for the manufacture, use and distribution of algoterine. Concerned about ensuring a price for the drug that is affordable for the population, officials from the SMH have summoned GR executives to its offices for a meeting ahead of their negotiations. At the same time, representatives of IPE are in town to assess the possibility of relocating some of its manufacturing operations to an LDC, with a view to taking advantage of extensions in TRIPS Agreement implementation phases for LDCs. Additionally, IPE is interested in TRIPS flexibilities which give each TRIPS Member the right to develop their own methods to bring themselves into conformance with TRIPS obligations. According to the Doha Declaration, TRIPS flexibilities also give each Member the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted.

Meanwhile, the regional office of AIDS Watch, an international NGO, has received significant press coverage of late, especially due to its criticism of how the governments of the region have lagged behind in responding to the AIDS crisis, and are paying particular attention to the negotiations between GR and BPC. NGOs such as AIDS Watch have proven instrumental in ensuring social interests and essential human rights are considered and protected during negotiation processes. It is also known that AIDS Watch has contact with International Dispensary Association (IDA) whose mission is to ensure affordable prices of essential drugs around the world.

Confidential Information for each of the teams is provided herewith. Copies of the relevant provisions of the laws of Sotowa Republic and of the Kingdom of Kando are also made available as background materials to the participants. All participants should also have a copy of a sample license agreement as part of the guide and training materials (annex I).

Demographic Information

Sotowa	
Population	24,707,817
Median Age	18.2 years
Population Growth Rate	2.57%
Birth Rate	39.72 births/1,000 population
Death Rate	14.02 deaths/1,000 population
Net Migration Rate	0 migrant(s)/1,000 population
Life Expectancy	46.93 years
HIV/AIDS Prevalence Rate	7.7%
Literacy Rate	85.1%
GDP Purchasing Power	\$37,890,000,000
GDP Per Capita (real)	\$530
Population Below Poverty Line	50%

Kando	
Population	6,005,250
Median Age	17.4 years
Population Growth Rate	2.3%
Birth Rate	45.76 births/1,000 population
Death Rate	23.03 deaths/1,000 population
Net Migration Rate	.23 migrants/1,000 population
Life Expectancy	40.22 years
HIV/AIDS Prevalence Rate	9%
Literacy Rate	29.6%
GDP Purchasing Power	\$4,939,000,000
GDP Per Capita (real)	\$160
Population Below Poverty Line	68%

Arunga Economic Community	
Population	76,782,667
Median Age	17.8 years
Population Growth Rate	2.43%
Birth Rate	42.74 births/1,000 population
Death Rate	18.53 deaths/1,000 population
Net Migration Rate	.17 migrants/1,000 population
Life Expectancy	43.58 years
HIV/AIDS Prevalence Rate	8.4%
Literacy Rate	57.35%
GDP Purchasing Power	\$107,072,500,000
Ave GDP Per Capita (real)	\$345
Population Below Poverty Line	59%