South Africa vs. the Drug Giants
A Challenge to Affordable Medicines
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Executive summary

On 5 March 2001, some of the world’s largest pharmaceutical companies, including GlaxoSmithKline, will take the South African government to the Pretoria High Court over the terms of its Medicines Act. This Act was passed by Parliament in 1997, and signed by former President Mandela. It seeks to promote more affordable medicines, but has not come into effect because of this legal challenge. The companies have chosen to pursue the case despite the devastation caused by the public health crisis in South Africa, sparking an international outcry. In the intervening period 400,000 people have died from AIDS related diseases, partly because of the high cost of treatment.

The Act contains provisions which could allow the South African Government to:

- use ‘parallel importing’\(^1\) to obtain patented life-saving medicines from countries where they are sold more cheaply;

- authorise imports of generic versions of patented medicines for non-commercial government use, through compulsory licenses (although legally this is not clear).

- adopt measures to ensure that pharmacists dispense cheaper generic copies where doctors have prescribed more expensive brand-name drugs;

- establish a pricing committee to introduce a transparent pricing system for all medicines.

The 39 companies involved in this case include the five leading drug companies in the HIV/AIDS field: GlaxoSmithKline, Merck and Co, Bristol-Myers Squibb, Roche, and Boehringer Ingelheim. Last year these companies had global sales of well over three times the South African government’s national budget. Their profits were almost twice as much as the government’s total combined expenditure on education and on health and welfare.

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\(^1\) Parallel importing means that the South African government would be allowed to source the lowest-price patented products on the global market, rather than take the price determined for the South African market by the pharmaceutical giants. (Note: this has nothing to do with generics; it simply relates to the free trade of patented-protected products.)
In the court application the companies argue that the Act is unconstitutional because it deprives them of their right to property and contravenes World Trade Organisation (WTO) patent rules. Oxfam believes that these claims are bogus because the South African government has a higher constitutional duty to progressively improve health care for everyone, and the measures permitted by the Act are allowable under WTO rules.

The South African Constitution states that ‘everyone has the right to have access to health care services’. The measures in the Medicines Act are vital tools to help the government meet this goal by helping to reduce the price of medicines.

There are many challenges to improving health care in South Africa. Budget constraints, poor-quality training, and inadequate health-care infrastructure are all important. Some elements within the government did not respond adequately to the HIV/AIDS crisis in its early stages. But the high price of medicines is also a major obstacle. Many of the medicines needed to treat South Africa’s major killers are priced far beyond the reach of the government and of most individuals.

In South Africa over 4.5 million people are infected with the HIV virus. There are 1700 people infected every day, of whom 200 are babies. Yet nearly all the key anti-retrovirals used to suppress the HIV virus are under patent and sell at prices ranging from four to twelve times the price of generic equivalents available on the world market. Important anti-infective drugs are also under patent. Large numbers of people suffer from AIDS-related tuberculosis, and from sexually transmitted diseases, a growing proportion of which are multi-drug resistant and require expensive new patented drugs to treat them.

In Brazil, the government has helped to halve the death rate among HIV/AIDS sufferers by introducing free access to anti-retrovirals. This has been achieved in part through the local manufacture of cheaper generic medicines made possible because of Brazil’s pre-TRIPS patent legislation. This has knocked down the price of anti-retroviral medication by three quarters.

In South Africa triple therapy costs US$10000 per person per year at current patented prices. If the South African government attempted to treat 700,000 people, a similar proportion of people to those treated in Brazil - this would cost US$7 billion at current patented prices, equivalent to 27 times the government’s entire public-sector budget for medicines.

The pharmaceutical companies’ complaint that section 15C of Act 90 (1997) contravenes the WTO Agreement (the Agreement on Trade-Related Intellectual Property Rights, known as TRIPS) does not stand up to scrutiny. TRIPS is neutral on parallel imports, and explicitly permits compulsory licenses, two facts that even the US government and the European Commission have come to accept. The concern of the pharmaceutical companies that the use of parallel importing would undermine incentives to conduct research and development (R&D) into new medicines is also puzzling, since the African market as a whole represents only one per cent of the multinational companies’ drug sales and does not therefore significantly influence R&D decisions.

The March 2001 court case constitutes an unwarranted intrusion by the companies into South African attempts to protect public health, and an attempt to interpret the TRIPS Agreement in their own interests. If the pharmaceutical companies win the case, this will:

- Limit the South African government’s ability to improve poor people’s access to vital medicines. The three-year delay caused by the court case has already taken its toll. If the South African government had been able to afford a similar package of care as that given to HIV/AIDS sufferers in Brazil, over 300,000 lives could have been saved since the court case began.
• Send a chilling message to other developing-country governments not to use the existing public-health safeguards within TRIPS, nor to implement national pro-poor health legislation, if these affect the patent privileges of the pharmaceutical companies, even if they are WTO-compliant.

The pharmaceutical industry highlights their own initiatives to reduce prices and donate key medicines to cash-strapped countries. Such efforts are a welcome recognition that price plays a key role in determining access to medicines. They may also help increase the number of people being treated. However, they are not a complete or sustainable solution. Such initiatives are selective, sometimes temporary, and always reliant on company goodwill.

The South African government’s ‘crime’ has been to introduce a law which allows it to avoid paying the high prices that international pharmaceutical companies are asking for their patented medicines in order to help reduce the incalculable suffering of millions of people. The court case will be a legal test of whether the health of these people, or harmful monopolies on life-saving medicines, take precedence. Oxfam is calling for:

• The pharmaceutical companies to stop the bullying and withdraw from the court case.

• The European Union and the USA to publicly support the South African government’s right to use parallel importing and compulsory licensing in this case.

• The international community to agree that the health crisis in South Africa constitutes a national emergency. This would allow the government to use compulsory licensing without first going through prolonged negotiations to acquire voluntary licences, and without fear of the threat of trade sanctions.

• The international community to provide political and financial backing to the efforts of South Africa (and of other developing countries facing similar health crises) to improve access to vital medicines.

A global movement seeking changes to patent rules and corporate behaviour, in order that medicines become more accessible in developing countries, is coalescing around this trial. Oxfam is part of the movement supporting the Global Day of Solidarity on 5 March, which has been initiated by South Africa’s Treatment Action Campaign (TAC), a grassroots advocacy organisation campaigning to make anti-AIDS medicines affordable in South Africa.
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The challenge of disease in South Africa

The HIV epidemic in South Africa is one of the fastest growing in the world. There are now approximately 4.5 million South Africans living with HIV. Over 1700 people are infected with HIV each day, 200 of whom are babies. The HIV epidemic is severely affecting the young, black, and economically impoverished populations of South Africa.

Young women have the highest rate of infection and are particularly vulnerable because of their economic dependence on men and because of the high levels of sexual violence. There are approximately 500,000 clinically ill AIDS patients, and in 1999 an estimated 250,000 people died of HIV/AIDS.

By 2005, there will be almost one million orphans under the age of 15 whose mothers have died of AIDS. Average life expectancy is expected to fall from approximately 60 years in 1998 to 40 years in 2008.

HIV/AIDS is not the only problem. South Africa also has a very high incidence of tuberculosis, with 100,000 new cases being diagnosed each year. A growing proportion of these cases is multi-drug resistant and will require new forms of antibiotics in the future. TB is fueled by the HIV/AIDS epidemic and is the most frequent cause of death in people living with HIV. In South Africa approximately 40–50 per cent of TB patients are infected with HIV. In some hospitals, HIV prevalence in TB patients has been recorded at over 70 per cent.

There are also high levels of sexually transmitted diseases, which cause suffering and damage women’s reproductive health, and which are a major determinant of HIV transmission.

Malaria is a smaller but growing problem afflicting South Africans living on the borders with Zimbabwe and Mozambique. Eighty per cent of cases in one province are drug resistant to the old but affordable oral treatments of chloroquine and sulfadoxine-pyrimethamine.

Poor people’s access to health

On coming to power in 1994, the government inherited a racially divided and unequal health sector. On the one hand there was the private health sector, consisting of a high-tech system serving 20 per cent of the population, who were largely white. This accounted for 49 per cent of total health-care expenditure and 80 per cent of national spending on medicines. On the other, there was the public sector, which served the remaining 80 per cent of the population, who were largely black. This accounted for only 51 per cent of total health-care expenditure and 20 per cent of total drug expenditure. In principle, everyone has access to the government’s public service, but in practice it is under-funded with poorly trained staff.

The government has concentrated its efforts on improving health services and infrastructure for the majority of people who depend on government health services. Particular emphasis is given to providing universal access to primary health care, especially for women and children.
An important element of this strategy is the essential medicines policy, which seeks to ensure an adequate and reliable supply of safe, cost-effective medicines of acceptable quality to all citizens of South Africa, as well as the rational use of medicines by prescribers, dispensers, and consumers.

Despite this, high prices still posed a significant obstacle to improved health care which led to the introduction of the 1997 Medicines Act (the Medicines and Related Substances Control Amendment Act of 1997). Some vital medicines, such as anti-retrovirals, are not included in the essential drugs list because of their high price. Moreover, generic medicines have been sold to the South African government at prices some ten per cent higher than those of IDA/UNICEF. In the private sector the lack of control over medicine prices and dispensing practices has also resulted in high prices.

The government has rightly been criticised for its response to HIV/AIDS in its early stages. However, it has recently developed a national Strategic Plan for HIV/AIDS and sexually transmitted disease which includes prevention, treatment, care and support, human and legal rights, monitoring, research, and surveillance. It has also embarked on an ambitious country-wide pilot-testing programme of using anti-retroviral therapy to prevent mother-to-child transmission of HIV, following a promised donation of Nevirapine from Boehringer Ingelheim.

The problem with patented medicines

South Africa introduced laws affording high levels of patent protection over 20 years ago. This has meant that many recently developed HIV/AIDS medicines are under patent, as well as new or improved treatments for multi-drug resistant tuberculosis, sexually transmitted diseases, and malaria.

Treatments for HIV/AIDS

Anti-retrovirals are vital to suppress the HIV virus and prevent mother-to-child transmission of HIV. Data from the USA illustrates that anti-retroviral therapy has reduced AIDS-related mortality by 75 per cent over a three-year period. Yet the patents on key anti-retrovirals have meant that they sell in South Africa at prices ranging from around four to twelve times above the price of the cheapest generic equivalent available on the world market.

Anti-fungal medicines, important for treating the opportunistic diseases associated with HIV/AIDS, have also until recently been priced out of reach of the South African government. Fluconazole, a drug vital in the treatment of cryptococcal meningitis and oesophageal thrush, is patented by Pfizer in South Africa until 6 June 2002. The price of fluconazole in September 1999 was US$9.34 per unit, compared with US$0.60 in Thailand. Médecins sans Frontières has estimated that if South Africa were to import generic fluconazole from Thailand, the cost of treating 10000 patients would decrease from US$34.8 million to US$2.16 million per year of maintenance treatment.²

The Treatment Action Campaign, a local group campaigning for affordable HIV/AIDS medicines in South Africa, asked the government to issue a compulsory licence to produce or import fluconazole. When nothing happened, TAC imported 5000 capsules of a generic version Biozole from Thailand. This broke two laws: the Medicines Act (for importing a non-registered product) and the Patent Act (for infringing Pfizer’s patent rights). The Medical Control Council (MCC) charged TAC with breaching the Medicines Act. Later, TAC successfully obtained an exemption from the MCC, allowing it to import unregistered Biozole to their clinic in Cape Town. Pfizer has not acted on this patent infringement. On 1 December 2000 Pfizer and the Department of Health signed an agreement in which Pfizer will donate fluconazole to South Africa’s public sector hospitals for cryptococcal meningitis and oesophageal thrush.

**The New Generation of Diseases**

The problem with patents goes beyond HIV/AIDS. In common with other countries, South Africa faces a growing problem of multi-drug resistant disease. Oxfam fears that a stringent interpretation of patent rules, of the kind sought by the pharmaceutical companies, will result in longer periods of high prices for the new drugs needed to treat these diseases, because it will prevent generic competition. This will price these drugs out of reach of the government, and thus seriously reduce their access by poor communities.

Up to four per cent of TB cases in South Africa are multi-drug resistant. Treatment is extremely expensive: it costs US$3250 per treatment for medicines alone, and takes 12–18 months.

Coartemether is important for treating multi-drug resistant malaria. But the Novartis drug is under patent and expensive. Novartis has recently offered to reduce the price from US$10 to US$3.60.

Ciprofloxacin, patented by Bayer in South Africa, is an important anti-bacterial treatment for sexually transmitted diseases, childhood shigellosis (bloody diarrhoea), and chest infections. It can also reduce the transmission of HIV/AIDS. In South Africa it costs R5.6/500mg tablet, which is twelve times the cost of the generic equivalent in India, where it is made by 147 generic companies, including Cipla, and sells at around R0.46.

**Patent law and the Medicines Act**

South Africa’s 1978 Patent Act introduced a high level of patent protection for pharmaceuticals. The government brought the patent law fully into compliance with TRIPS in 1997 (The Intellectual Property Laws Amendment Act no. 38). At the same time the government introduced the Medicines and Related Substances Control Amendment Act no. 90, which was intended to provide the legal framework for its national drugs policy. The most controversial element is clause 15C, which allows the government to override patent rights in the pharmaceutical sector on public-health grounds. It states that:
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 in the Patents Act 1978 (Act no 57 of 1978) determine that the rights with regard to any medicine under a patent granted in the Republic shall not extend to acts in respect of such medicine 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 already 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).’

The main purpose of this clause appears to be to give the Health Minister the authority to permit the use of parallel importing, an option which was not included in the South African Patents Act. The Patent Act already allows for compulsory licensing in the case of abuse of patents rights, but section 15C of the Medicines Act could also possibly allow the Health Minister, rather than the Commissioner of Patents (a judge in the Patent Office), to issue a compulsory licence. This could open the door for the government to use the fast-track procedure for compulsory licensing available under TRIPS in the event of a national emergency. In such cases, this procedure allows governments to move straight to compulsory licensing without having first made efforts to obtain authorisation from the patent holder.

The Medicines Act contains other measures which seek to contain health-care costs. These include:

- Measures to ensure that pharmacists dispense cheaper generic medicines rather than expensive brand-name versions.
- The establishment of a pricing committee to introduce a transparent pricing system for all medicines.

The court case

Background to the case

Soon after South Africa introduced the 1997 Medicines Act, the US government put South Africa on its ‘Special 301’ trade watch list and threatened trade sanctions if the Act was not repealed. This followed heavy lobbying by the Pharmaceutical Research and Manufacturers of America (PhRMA), the US trade association representing large pharmaceutical drug companies such as GlaxoSmithKline and Bristol-Myers Squibb. The USTR Special 301 report on South Africa of 30 April 1999 essentially recycled PhRMA complaints about the South African government’s consideration of compulsory licensing and parallel imports. The report even criticised South African representatives at the World Health Organisation who were calling for a reduction in the level of protection provided to pharmaceuticals within TRIPS. As James Love, Director of the Consumer Project on Technology, wrote in a letter to Vice President Gore: ‘the exercise of free speech in international forums is an astonishing basis for trade sanctions.’
In March 1988 the then Vice-President of the European Commission, Sir Leon Brittan, also wrote to the then Deputy-President, Thabo Mbeki, arguing that the Act ‘would appear to be at variance with South Africa’s obligations under the WTO TRIPS agreement … and its implementation would negatively affect the interest of the European pharmaceutical industry.’

However, on 1 December 1999, and following a public outcry in the USA, the US government dropped South Africa from its ‘301 watch list’, thus signalling a change of policy. On 10 May 2000 President Clinton issued an Executive Order stating that the USA would no longer threaten trade sanctions against countries in sub-Saharan Africa if they were using TRIPS compliant measures, such as compulsory licensing or parallel imports, to improve access to HIV/AIDS medicines.

Subsequently, a statement by the European Trade Commissioner, Pascal Lamy, in September 2000 noted that ‘the TRIPS Agreement provides the necessary flexibility to protect public health concerns, including through recourse, under certain conditions, to compulsory licensing. While the Commission attaches great importance to all WTO members adopting intellectual property legislation which is fully compatible with their international obligations, it does not push countries to adopt legislation that is more stringent than the TRIPs Agreement requires’.

**The case against the Medicines Act**

In the application for the court case, the Pharmaceutical Manufacturers Association of South Africa and the 39 pharmaceutical companies argue that the 1997 Medicines Act is unconstitutional on several counts.

They argue that Section 15C of the 1997 Medicines act allows the Health Minister to deprive owners of intellectual property, or to expropriate it without compensation. This, they argue, conflicts with Section 25 of the Constitution.

The companies also claim that section 15C is not TRIPS-compliant and is therefore unconstitutional. They say that it is ‘discriminatory in respect of the enjoyment of patent rights in the pharmaceutical field which is in conflict with the provisions of Article 27 of TRIPS’. Article 27 of the TRIPS Agreement states that patents ‘shall be enjoyable without discrimination … as to the field of technology’. The companies argue that as TRIPS is a binding international agreement reflected in South Africa’s Patent Act of 1997, the Medicines Act is in conflict with the Constitution (Sections 44 (4), 231(2) and 231(3)).

The companies are also contesting the Act’s provision on generic substitution which they claim, among other things, discriminates unfairly in favour of generic manufacturers. This practice requires pharmacists to dispense generic substitutes for branded medicines if these are cheaper than the branded product, unless expressly forbidden to do so by the patient, the doctor, or the Medicines Control Council. The companies argue that this is in conflict with Section 9 of the Constitution which states that everyone has the right to equal protection and benefit from the law. They also argue that it interferes with the pharmacists’ freedom to trade (Section 22).

\[3\] In addition to these complaints, the US trade association of pharmaceutical companies, PhRMA, has said that ‘clause 15 c (b) allows for parallel importation, a violation of TRIPS article 28 which while not actionable through WTO dispute settlement procedure, poses a serious threat to the viability of American pharmaceutical investment in South Africa’. (http://www.phrma.org/policy/aroundworld/special301/safrica.phtml, 5/101)
The companies also oppose the Act’s provision for a Pricing Control Committee which they say also interferes with their right to trade and conflicts with Section 22 of the Constitution.

The Chief Executive Officer of the Pharmaceutical Manufacturers’ Association of South Africa (PMA) was quoted in August 2000 as saying that ‘underpinning the PMA’s rejection of attempts to generally abrogate patent rights is our unflinching belief that patent protection does not stand in the way of access to medicine and health care... sound economic policies and sufficient healthcare funding, government commitment and political will, adequate infrastructure and capacity are equally important for access to improve’.

**The case for the Medicines Act**

The government has a constitutional duty to progressively improve health care for its people. The Constitution states that ‘everyone has the right to have access to health care services’, and that ‘the state must take reasonable legislative and other measures, within its available resources, to achieve the progressive realisation of each of these rights’. The Medicines Act is a vital part of the government’s efforts to bring down the price of medicines, in order to improve the availability of affordable medicines and quality health care for poor communities, reduce the devastating rates of HIV/AIDS, tuberculosis, and other infectious diseases, and address the enormous health problems and inequalities inherited from the apartheid era.

In the public sector, many people are deprived of access to vital patented medicines because of their price. The high cost of these medicines also limits the budget available to distribute cheaper generic medicines for other diseases. Lower prices would also benefit the 20 per cent of people who rely on private-health schemes by allowing them to complete treatments rather than abandon them when medical aid runs out.

Contrary to company claims, the measures permitted by section 15(c), including parallel importing and possibly compulsory licensing of imports, are both allowed under the WTO TRIPS Agreement subject to certain conditions and if included in national legislation. TRIPS is neutral on parallel importing, and explicitly allows compulsory licensing under certain, albeit restrictive, conditions. Both measures are used in developed countries. The companies’ argument that section 15C of the Medicines Act is discriminatory, because TRIPS Article 27.1 requires patent rights to be enjoyed in all fields of technology, is contradicted by a WTO panel report on the recent Canada-Generic Pharmaceuticals case. This stated that ‘Article 27 does not prohibit bona fide exceptions to deal with problems that may exist only in certain product areas’.

In answer to the pharmaceutical companies’ criticisms that the wording of clause 15C is too wide, the government has insisted that it has no intention of abrogating patent rights indiscriminately, and has repeatedly indicated its intention to use such instruments in a TRIPS-compliant manner. It has offered to enter into discussions with the companies on the wording of section15(c), but has indicated that it would not shift on the policy principles underlying the clause.

In the case of generic substitution, the measure only applies when the patent on the branded medicine has expired or is not in force. It would not therefore affect the sales of products still protected by a patent. Neither would it unduly restrict the right of companies selling branded products to trade. It is a common practice in Canada, Holland, Japan, and certain states in the USA.
Company price reductions and donations

During the past year, as disquiet over the impact of high prices on access to medicines in developing countries has grown, a number of companies have offered key medicines at substantially reduced prices or as donations. Many of these are bilateral agreements between individual companies and governments, and concern a specific medicine. The most concerted initiative is part of the UNAIDS ‘Accelerating Access to HIV/AIDS Care and Treatment Initiative’, which brings together five companies, all of which have pledged to supply cut-price anti-retrovirals to governments as part of a national AIDS plan.

Following a campaign by South African activists, the American company Pfizer offered to provide fluconazole free of charge for people living with HIV/AIDS. However, Pfizer wanted it to be used only for the treatment of meningitis – not thrush. There was also a time limit, and the offer was structured as a clinical trial, which would mean difficult reporting and training requirements. Following the withdrawal of these conditions, the South African government has now accepted the donation, which will soon be available.

More recently, Boehringer Ingelheim has lowered prices of Nevirapine, a drug under patent in South Africa until 2010, which is vital to prevent mother-to-child transmission (MTCT). The Department of Health has expanded its programme testing the efficacy of anti-retroviral medicines in minimising mother-to-child transmission to over 20 pilot sites throughout the country. Boehringer will donate the drug free of charge to the MTCT programme for five years. When used in triple treatment for HIV, the company has reduced the price by 70 per cent to US$ 1.5 for a daily dose. However, sustainability at the end of the 5 year period is not guaranteed.

These efforts are a welcome recognition that price plays a key role in determining access to medicines. They will also help to increase the number of patients being treated. However, they are not a complete or sustainable solution. Such initiatives are selective, sometimes temporary, and always reliant on company goodwill. The 5 companies offer to reduce prices of antiretrovirals is a step in the right direction. But the offer is untransparent about prices, is limited to ARVs and the prices offered to Senegal are still higher than those offered by Cipla, an Indian based generic manufacture.

Developing-country governments such as South Africa, which face public-health crises and restricted budgets, cannot rely on such measures alone. They need a long-term, reliable supply of the cheapest possible, high quality medicines. If the South African government determines that this can be best achieved by using the WTO safeguards or other national measures, then it should be free to exercise discretion about the appropriate balance between the urgent health needs of its people and the intellectual property rights of pharmaceutical companies. The companies’ bullying tactics to stop the South African government using such measures put into question their stated commitment to improving access to medicines.
Recommendations

The March 2001 court case will be a legal test of whether the health of people in South Africa, or harmful monopolies on life-saving medicines, take precedence. Oxfam is calling for:

- The pharmaceutical companies to stop the bullying and prove their commitment to improving access to medicines by withdrawing from the court case.

- The European Commission and the USA to publicly support the South African government’s right to use parallel importing and compulsory licensing in this case.

- The international community to agree that the health crisis in South Africa constitutes a national emergency. This would allow the government to use compulsory licensing without first going through arduous and prolonged negotiations to acquire voluntary licences, and without fear of the threat of trade sanctions.

- The international community to provide political and financial backing to South Africa’s efforts to improve access to vital medicines and improve its health care system.

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