Oxfam Update on South African Court Case

South Africa vs. the Drug Giants

April 2001

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On 5 March 2001, 39 of the world's largest pharmaceutical companies took the South African government to court over the terms of its 1997 Medicines Act. The Act was intended to provide a legal framework within which medicines could be made more affordable in South Africa. However, it has not come into effect because of this legal challenge. The companies' decision to pursue the legal proceedings initiated in 1997, despite the devastation caused by South Africa's public-health crisis, has sparked international condemnation. As the presiding judge noted, this is a landmark case which has implications far beyond South Africa.

This short update builds on Oxfam's previous background briefing issued at the start of the trial. (*South Africa vs The drug Giants: A Challenge to Affordable Medicines* is available on Oxfam's web site: Oxfam.org.uk/cut the cost/index.html).

Oxfam is calling for:

1. The pharmaceutical companies to withdraw from the court case.

2. The European Union and the USA to support publicly the South African government's right to use parallel importing and compulsory licensing.

3. A strengthening of public-health safeguards in TRIPS so that governments can override patents on public-health grounds without facing the threat of trade sanctions or legal pressures.

4. Longer transition periods for developing countries based on the achievement of development milestones rather than arbitrary dates.

5. A substantive review of TRIPS, which includes revisiting the issue of the length and scope of patent protection for medicines.

6. A massive increase in public financing and international aid to help South Africa and other developing countries tackle their public-health crises.

LATEST EVENTS

In a dramatic turn of events on the second day of the trial, the judge agreed to allow the Treatment Action Campaign (TAC), a local voluntary network which campaigns for affordable treatment for people with HIV/AIDS, to become an *amicus curiae* (friend of the court). This meant that, despite strong opposition from the companies, the court was willing to consider broader issues raised by the legal case, including the high price of patented medicines. Consequently, the court case was suspended to allow the companies sufficient time to respond to the new evidence.

The court case has provoked demonstrations, petitions, and letters calling on the pharmaceutical companies to withdraw. Ministers of various European Union governments, including Germany, denounced the companies' legal strategy and called on them to end the proceedings. The European Union parliament, with the full support of all political groupings, also passed a resolution calling for the companies to withdraw, and for the European Commission to help developing countries use the safeguards contained within the World Trade Organisation (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).

The publicity surrounding the court case intensified the price war on anti-retroviral drugs both between the pharmaceutical giants, and between them and the generic drug companies. Large companies such as Merck cut drug prices as they sought to recoup some public support, to blunt the offers from generic-drug companies, and to stave off growing public disquiet about patents on medicines. Raymond Gilmartin, Merck's Chairman and Chief Executive, said: 'If we don't solve the drug access problem then our intellectual property is at risk'.

As a result of competition, the prices offered by companies for triple therapy in South Africa have fallen from the initial patented price of approximately US$10,000 per patient per year to approximately US$1000. Yet the offers from the pharmaceutical giants do not nearly match the recent offers from generic companies in India. Aurobindo, an Indian generic company, recently offered triple-therapy regimen for US$295 per person per year.

The hearing will resume on 18 April and last until 25 April. The final judgement will be issued three to four months later. It is vital that the rights of governments to adopt national policies and use the safeguards within TRIPS, which allow them to improve the affordability of medicines, are upheld.

Background

Over 4.5 million people in South Africa are infected with the HIV virus. The vast majority of people infected with HIV do not have access to effective treatment. Nearly all the key anti-retrovirals necessary to suppress it are under patent, and sell at prices ranging between four and twelve times the price of generic equivalents available on the world market. Important anti-infective drugs are also under patent. However, the problem extends beyond HIV/AIDS. 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 for treatment. For example, Ciprofloxacin, patented by Bayer in South Africa, is an important anti-bacterial treatment for sexually transmitted disease, childhood shigellosis (bloody diarrhoea) and chest infections. In South Africa it costs R5.6/500mg tablet, which is twelve times the cost of the generic equivalent in India where it sells for around R0.46.

Other factors contribute to the problem of access to medicines, including lack of finance and inadequate health-care infrastructure. The South African government was rightly criticised for its initial response to HIV/AIDS. The companies have also criticised it for spurning their offers of discounted or donated drugs. It has, however, recently developed a national HIV/AIDS strategy, and accepted donations of fluconazole from Pfizer for use against opportunistic infections, and of Nevirapine from Boehringer Ingelheim for a programme to reduce mother-to-child transmission of HIV.[1]

[1] Registration of Nevirapine has not yet been finalised by the Medical Control Council. The South African government says that this is due to the government's request that Boehringer agrees to monitor the medicine.

The 1997 Medicines Act includes measures which would allow the government, among other things, to:

- 'shop around' for cheaper patented medicines abroad (parallel importing)
- ensure that pharmacists dispense cheaper generic copies where doctors have prescribed more expensive brand-name drugs
- introduce a transparent pricing system for all medicines.

In their original court application the companies argued that clause 15c of the Medicines Act was unconstitutional, because, if implemented, it would introduce broad and arbitrary powers which would:

- allow the Health Minister to override provisions contained within the 1978 South Africa Patents Act
- deny companies their right to property without compensation
- breach South African commitments under the WTO patent rules

More generally, the companies have repeatedly argued that price is not the primary factor limiting people's access to medicines, and that high levels of patent protection will stimulate research and development (R&D) into tropical and infectious diseases.

The South African government has responded by saying that it has a constitutional obligation to protect its citizens' rights to health. It has repeatedly stressed that it only intends to use the measures in the Medicines Act in a TRIPS-compliant way.

TAC, Médecins sans Frontières, Action for Southern Africa, Oxfam, and others around the world have supported the Medicines Act, arguing that it enables the government to fulfil its higher obligations to protect the rights to health and life. This is in keeping with both the South African constitution and international conventions on human rights.

In its recent background briefing, Oxfam said that while a range of factors combine to block people's access to new medicines, the high cost of patented medicines is a central obstacle. Along with other commentators, Oxfam has also pointed out that the TRIPS agreement allows governments to override patents on public-health grounds, and that TRIPS takes a neutral position on parallel importing (facts recognised by both the United States and the European Commission). Equally, there is no evidence that strong patent protection in developing countries will materially increase the incentives for R&D in these countries, because their market size is so small. Oxfam and others have argued instead for other incentives including massive targeted government investment in R&D.

Oxfam believes that the companies' legal proceedings are an unwarranted intrusion into the democratic process of law in South Africa, and a dangerous attempt to interpret the TRIPS agreement in their own interests. If they win the case, this will severely compromise the government's duty to provide its citizens with access to affordable medicines. It would also send a chilling message to other governments not to use the existing safeguards in TRIPS, nor to implement national pro-poor health legislation, even if these are WTO-complaint.

RECENT COURT SUBMISSIONS

TAC's *Amicus Curiae* Brief

In its court application, TAC argued that it should be allowed to become an *amicus curiae* to the court, because the rights of its members are being directly threatened by the pharmaceutical companies' action (see www.tac.org.za). Its application states that 'the constitutional rights to equality, dignity, life, access to health care services and the rights of children of many people living with HIV/AIDS, and in particular TAC volunteers, will be directly affected by the outcome of the proceedings'.

> I am caring for people every day who are living with AIDS. Not one of them is able to afford to pay for treatment and that means not one single person who is living with HIV/AIDS in my area that is getting any medication unless they are on a clinical trial. Most of the people I have cared for have been told to go home and die because there is nothing to help them. (Affidavit by Mrs Patricia Dove)
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> The doctor said the medication (anti-retrovirals) might benefit me but if I wanted to go on the drugs it would cost me R1200 a month for one kind of treatment and R600 a month for another. My wages are about R500 a fortnight for gardening: if I buy the medication then how are my family going to eat. So I am not receiving any treatment…The bottom line is that people who are living with AIDS should not pay for this epidemic with their lives. I say to the government and the drug companies: give me the drugs I need and let me support my family. (Affidavit by Mr Vernon Ogle)
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> The trial is for a year. I started on 17 January 2001. I feel okay now. I feel well…. I worry about what life will be like when Vernon [her husband who has HIV but is not eligible for a trial] has passed on and I am unemployed, unable to afford these drugs, unable to get a disability grant and trying to look after my child when he gets sick. My doctor explained to me that overseas you can get these drugs free but here we must pay so much money even though unemployment is so bad. I believe that the South African government should have the legal power to make cheaper medicines available to everyone who needs them. (Affidavit by Mrs Judith Ogle)

The TAC affidavits also point out that 'the costs of many medicines that are essential in the treatment of HIV/AIDS have been considered prohibitive in both the private and public-health sectors. Medicines have therefore not been widely provided. Without access to medicines, there is very little incentive for members of the public voluntarily to seek HIV counselling and testing. Without diagnosis, many people inadvertently transmit HIV during sexual intercourse. This chain of events contributes to the failure of the South African government to contain the epidemic'.

TAC argues that the government has a constitutional duty to improve access to medicines for all people in South Africa, and in particular for people living with HIV, and that the measures in the Medicines Act are essential to help the government fulfil this duty.

TAC's submission contends that the measures contained in the Act are both constitutional and TRIPS-compliant. The measures are constitutional because they do not infringe the constitutional rights of the applicants. They merely create a legal framework to prevent pharmaceutical companies from making excessive profits out of the sale of medicines in South Africa at the expense of the rights of citizens to life, dignity, and health care. If there were there to be any infringement of the company's rights, this

would be permissible under Article 36 (1) of the constitution, which states that the Bill of Rights may be limited in terms of law of general application as long as it is reasonable and justifiable to do. TAC argues that the measures are reasonable and justifiable because the rights to life and dignity have higher precedence than any other rights in the constitution.

With regard to the question of whether the measures are TRIPS-compliant, TAC points out that the TRIPS Agreement allows governments to override patent rights on public-health grounds (among others) and takes a neutral position on parallel importing. TAC also argues that the companies are ignoring South Africa's other international obligations imposed on them by the International Convenant on Economic, Social and Cultural Rights (including the right to health), the Convention on the Elimination of all forms of Discrimination Against Women, and the Conventions on the Rights of the Child.

The Companies' Response

The companies opposed TAC's application to become an *amicus curiae*, arguing that the question of whether medicines are too expensive or not is irrelevant to the main court application, which is supposed solely to determine whether or not company rights are infringed by measures in the Medicines Act. The judge accepted TAC's application, but he also accepted the companies' demand to have time to prepare a response to this new evidence.

In their response to TAC's *amicus curiae* briefing, the companies lodged papers at the Pretoria High Court on Friday 30 March which alleged that the government had spurned offers of drug discounts and donations. Mirryena Deeb, representing the Pharmaceutical Manufacturing Association (PMA) of South Africa, said in her affidavit that 'to the extent that prices of medicines do enter the considerations, it is clear that [they] cannot play a significant role because the government declines to use these products even when offered for free'. She said that the failure to use anti-retrovirals was clearly 'a consequence of the policy of the department of health to attempt to manage the HIV and AIDS epidemic without the use of anti-retroviral medicine'.

The PMA also argued that most other countries have signed the TRIPS Agreement and that none of them had attempted to introduce legislation like that in South Africa. They also repeated their argument that strict patent protection is needed to maintain incentives for R&D.

OXFAM'S ANALYSIS AND RESPONSE

Oxfam shares TAC's view that that the measures contained in the South African Medicines Act are essential to help the government fulfil its constitutional duty to improve access to medicines for all people in South Africa. It believes that company discounts and/or donated medicines can be a welcome way of helping increase access to medicines. They are also an important recognition by the drug companies that price plays a key role in determining access to medicines. However they should not be seen as a substitute for legal frameworks, such as the Medicines Act or governments' legitimate use of the public health safeguards in TRIPS.

Company discounts and donations

The large pharmaceutical company's have made much of their offers of discounted HIV/AIDS medicines to South Africa. Some of these offers were made under UNAIDS' 'Accelerated Access to HIV/AIDS Care and Treatment Initiative' since May 2000. This initiative brings together five companies,

all of which have pledged to supply cut-price anti-retrovirals to developing country governments. The prices offered to the South African government were not made public, but the offers are likely to be similar to that accepted by Senegal of approximately US$1000 per patient per year for triple therapy.

Then on 6 March 2001 Merck & Co announced that it would reduce its prices for two of its important anti-retrovirals in Africa, on top of reductions already pledged last year. It will offer to developing countries with immediate effect Crixivan (indinavir sulfate) for US$600 per patient per year and Stocrin (efavirenz) for US500 per patient per year. (The combined cost for triple therapy will be higher as these drugs only constitute one part of the regime).

However, reliance on preferential pricing or on donations leaves governments dependent on companies' charity, providing only an *ad hoc* disease-specific approach to the problem, rather than a systematic solution. For example, most of the current offers apply exclusively to HIV/AIDS medicines despite the fact that South Africa, along with other developing countries, suffers from many other significant diseases. Drug-resistant strains of several common diseases are spreading fast, making existing medicines redundant. In future there are also likely to be new health risks unknown today. In Uganda it estimated that company discounts under the Accelerated Access Initiative are reaching just 1900 patients. This is in a country where around 1.4 million people are infected with HIV. In South Africa TAC is campaigning to ensure that company offers apply to the private, not just the government, sector.

Moreover, company discounts and donations provide no guarantee that the best price is being obtained. The PMA in South Africa has made much of the South African government's slow response to company offers and discounts. However, the prices for anti-retrovirals being offered by generic companies are well below the discounts offered by the large firms.[2] This strongly suggests that compulsory licensing of generic imports must form part of the solution to the health crisis in South Africa.

Further, the offers embroil governments that have limited capacity and resources in lengthy negotiations over individual medicines for individual diseases. Merck & Co Inc recently announced that it will abandon country-by-country negotiations under the Accelerated Access Initiative, which have dragged on slowly since last summer and resulted in only a small number of pricing agreements. To date, six African countries – Senegal, Rwanda, Uganda, Cameroon, Cote d'Ivoire and Mali – have accepted the companies' offers. As a result, Merck has decided to simplify the process by offering one price that it considers to be the lowest it can go.

Finally, discounts may come with conditions, as illustrated by a recent case in which Abbott Laboratories wanted to make its offer of cheaper AIDS drugs and a diagnostic test conditional on undertakings by recipients to forego the import of generic medicines. These kind of conditions fuel fears among governments that company offers are an attempt to undermine their legitimate rights to use the TRIPS provisions on parallel imports and compulsory licensing. The offers may also be time-bound and reversible. Pfizer's offer of fluconazole, for example, will be re-evaluated in two years when its patent expires.

These factors demonstrate that discounts and donations should not be seen as a substitute for national legal frameworks, such as the Medicines Act, which seek to find more sustainable and systematic solutions to the problems of price and access. Governments need the legal flexibility to obtain cheaper medicines on a range of diseases, not just HIV/AIDS.

[2] Shortly before the court case, the Indian manufacturer CIPLA offered to sell a triple-drug HIV cocktail to government programmes for US$600 per year per patient and to NGOs for US$350. Subsequently, Hetero and Aurobindo, both Indian generic manufacturers, have offered to sell triple-therapy regimen for US$347 and US$295 per patient per year respectively.

Nor should they be seen as an alternative to governments' legitimate use of TRIPS provisions for parallel importing and compulsory licensing. These provide governments with an important means of gaining access to cheaper medicines and promoting vital price competition. It is highly unlikely that the recent price reductions by large companies would have occurred without the competition from generic companies and public pressure.

The safeguards need to be strengthened so that governments can use parallel importing and compulsory licensing to without the threats they currently face of legal pressure or trade sanctions. Nevertheless, they are only a short-term option. Once countries like India are forced to comply with the TRIPS Agreement, generic competition for new medicines will be significantly delayed and their generic industry weakened. This will remove this vital check on the high prices of patented medicines. This suggests the need for a more substantive reform of WTO patent rules, including longer transition periods for developing countries and restrictions on the length and scope of patent protection for pharmaceutical products.

Financing Constraints

Even with the discounts on anti-retrovirals offered by the large companies under the UNAIDS 'Accelerated Access to HIV/AIDS Care and Treatment Initiative', the government would have only been able to treat a fraction of sufferers and even this would completely wipe out its drug budget. At the assumed price of approximately US$1000 per person per year, it would have cost the government US$700 million, or nearly three times its national drugs budget, to treat 700,000 people – a similar number to those now receiving treatment in Brazil. On the other hand, if the government were able to use compulsory licensing to gain access to the generic offer of US$295 per person per year recently offered by Aurobindo, the Indian-based generic company, it could treat the same 700,000 people at a cost of US$206 million, or the equivalent of 80 per cent of its drugs budget.

The generic offers obviously represent a substantial improvement on those from the drug giants, and yet, even if the government could gain access to these generic offers through the compulsory licensing of imports, it would still require a massive increase in public financing and international aid to ensure that resources were not being completely diverted from the treatment of other vital diseases.

For a government committed to providing universal and equitable health care, as mandated by the International Covenant on Economic Social and Cultural Rights (Article 12), these financing constraints pose a deadly dilemma. If the government accepts the current offers by the pharmaceutical giants, it would be able to provide treatment to only a fraction of the population and would divert resources away from other important diseases. But if it refuses the offers, it risks the accusation that it is failing to respond adequately to the crisis.

The need for compulsory licensing

The government's prime intention for introducing Clause 15c into the Medicines Act was to allow the use of parallel importing, an option which was not included in the amended South African Patents Act of 1978. Parallel importing is an important source of price competition and could provide savings to the government.

In contrast compulsory licensing is allowed on various grounds within the terms of the South African Patent Act, although the procedures involve the possibility of extended and expensive litigation over licensing requests which work to the companies' advantage.

If the companies had not brought legal proceedings, it is possible that Clause 15c of the Medicines Act could have been used by the Health Minister to use the fast track procedures under TRIPS to issue a compulsory licence.

However, the government's defence to the PMA's claim that Clause 15c is too broad has been to argue that it cannot be used for compulsory licensing.[3] This would appear to imply that in order to win the lawsuit, the government's legal team has abandoned any hope of using Clause 15c for compulsory licensing. Nevertheless the option of issuing a compulsory licence under the 1978 Patents Act is still open to the government and could be used.

TRIPS, developing countries, and R&D

The PMA response to TAC states that most other countries have signed the TRIPS Agreement, and that none has passed legislation similar to that in South Africa. However, what countries want to do, and what they feel able realistically to do, within the terms of the TRIPS Agreement, are very different. Prior to the 1999 WTO Ministerial Conference in Seattle, nearly 100 developing countries signed around 12 proposals to reform TRIPS, including one relating to health. At the request of the Africa Group, the WTO TRIPS Council has also recently agreed to a special TRIPS Council on health to discuss concerns about the agreement.

Yet in practice it is very difficult for developing countries to make use of even the limited flexibility offered under TRIPS. This is precisely because of the kind of legal pressure which the pharmaceutical companies are exerting. The USA also continues to pursue a highly aggressive bilateral policy on intellectual property under its Trade Act. Moreover, developing countries often lack the legal expertise and resources accurately to interpret and implement the agreement.

The companies argue that strong patent protection in developing countries is vital to provide the incentives for R&D into the diseases affecting people living in poverty. However, this argument has been contested by a number of organisations, including Oxfam. They argue that strong patents in developing countries will not significantly increase either the market potential or the incentive for R&D in developing countries, because the real incentive for R&D is profit, not patents. Latin America, often heralded as offering important markets, accounts for only four per cent of total global pharmaceutical sales. In sub-Saharan Africa this figure around one per cent. (For a full rebuttal of company arguments on R&D see Oxfam's Questions and Answers Sheet, *Implausible Denial: Why the Drug Giants' Arguments on Patents Don't Stack Up* available from our web site: Oxfam.org.uk/cut the cost).

CONCLUSIONS

This is a landmark case for the future of health care, not only in South Africa, but more widely in other developing countries. It will be an acid test of whether a government's right to protect people's health by obtaining the cheapest possible prices for medicines, in order to reduce the suffering of millions of people, will take precedence over harmful monopolies on life-saving medicines.

The price war which followed the court case demonstrates that the use of compulsory licensing to access cheaper generic offers, and a massive increase in public financing and international aid, will both be necessary if the South African government is to be able to address the serious health crisis in South Africa.

[3] The PMA has argued that Article 15c of the Medicines Act not only permits parallel imports but also allows the Health Minister to issue fast-track compulsory licences to compel a third party to manufacture patented drugs without negotiating adequate compensation or granting the right of appeal to the patent owner.

This report was produced by Oxfam as part of the 'Cut the Cost of Medicines' Campaign.

Oxfam has issued other publications as part of this Campaign:

- a shorter report entitled *Patent Injustice: How World Trade Rules Threaten the Health of the Poor*;
- *Dare to Lead*, an analysis of the responsibilities towards the developing world of GlaxoSmithKline, the UK-based pharmaceuticals company;
- *Fatal Side Effects: Medicine Patents Under the Microscope*;
- *South Africa vs. the Drug Giants - A Challenge to Affordable Medicines*;
- Thai Country Profile, *The Impact of Patent Rules on the Treatment of HIV/AIDS in Thailand*;
- *Implausible Denial: Why the Drug Giants' Arguments on Patents Don't Stack Up*.

All publications and more information on our campaign are available from Oxfam's campaign website (www.oxfam.org.uk/cutthecost).