

LITIGATION STRATEGIES TO GAIN ACCESS TO TREATMENT FOR HIV/AIDS: THE CASE OF SOUTH AFRICA'S TREATMENT ACTION CAMPAIGN

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With an estimated 4.7 million—or approximately one-in-nine—people living with HIV/AIDS, South Africa is in crisis.¹ While difficult to quantify the degree to which the epidemic will have an impact on South Africa,² it is generally accepted that it will result in a significant rise in morbidity and mortality,³ that an increase in illness and death will have negative economic and social consequences,⁴ and that the majority of AIDS-related deaths will be of young economically active adults.⁵ Because a sizeable percentage of South Africa's population fall within this category of people, the HIV/AIDS epidemic has the potential to devastate social, economic, and human development.⁶

It is also generally accepted that while the treatment of opportunistic infections may serve to delay the onset of AIDS, but for the intervention of combination antiretroviral therapy,⁷ HIV infection results in the gradual but inevitable decline and ultimate failure of a body's immune system.⁸ In almost all cases, only with access to antiretroviral drugs (ARVs) are people with HIV/AIDS able to lead longer and healthier lives.⁹

It is with this understanding that South Africa's Treatment Action Campaign (TAC) was launched on 10 December 1998, International Human Rights Day. While its main objective is to campaign for the development, adoption and implementation of a comprehensive national treatment plan for people with HIV/AIDS, TAC also works towards the prevention and

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¹ See South Africa, Department of Health, National HIV and Syphilis Sero-Prevalence Survey of women attending Public Antenatal Clinics in South Africa 2000, ¶ 4.14, available at <http://www.doh.gov.za/docs/reports/2000/hivreport.html> (last visited Mar. 27, 2002).

² ALAN WHITESIDE & CLEM SUNTER, AIDS: THE CHALLENGE FOR SOUTH AFRICA 82 (Cape Town: Human & Rousseau (Pty) Ltd/Tafelberg Publishers Ltd. 2000).

³ *Id.* at 81.

⁴ *Id.* at 82.

⁵ *Id.* at 70.

⁶ *Id.* at 58. See also Malcolm Steinberg et al., *Chapter 15: HIV/AIDS – facts, figures and the future*, in ANTOINETTE NTULI ET AL., EDS., SOUTH AFRICAN HEALTH REVIEW 2000 (Durban: Health Systems Trust, 2001), available at <http://www.hst.org.za/sahr/2000> (last visited Mar. 27, 2002).

⁷ Antiretroviral drugs, drugs that specifically target HIV infection itself rather than the opportunistic infections that are associated with HIV/AIDS, are combined in various different treatment regimens that collectively are known as highly active antiretroviral therapy or HAART. DARRELL E. WARD, THE AMFAR AIDS HANDBOOK: THE COMPLETE GUIDE TO UNDERSTANDING HIV AND AIDS 68-69 (1999).

⁸ *Id.*

⁹ Approximately five per cent of all people with HIV have survived for more than 10-12 years without antiretroviral treatment and without showing signs of HIV infection. *Id.* at 77.

obfuscation.”¹³ In addition, the state had sought to vilify civil society and generally to present every challenge as an insurmountable obstacle.¹⁴

Nevertheless, TAC’s starting point remains that the public health care system can, should and is constitutionally obliged to develop and implement a comprehensive national treatment plan, which includes the use of ARVs where medically indicated. Quite clearly, a national treatment plan is dependant on government making resources available for the strengthening and development of health care infrastructure. Our courts have held that proper planning is central to the marshalling of resources required for the implementation of such programmes. In *Treatment Action Campaign and Others v. Minister of Health and Others*, the Pretoria High Court held that “[o]nly if there is a coherent plan will it be possible to obtain the further resources that are required for a nationwide programme [to reduce the transmission of HIV from mother to child], whether in the form of a reorganisation of priorities or by means of further budgetary allocations.”¹⁵

I. THE ROLE OF LITIGATION

In a letter written in 1905 to jailed comrades, Lenin recommended that they participate in their trial only if it could be used for political agitation. If this was not possible, they were advised to remain silent. On the role of “the most reactionary people”—also known as lawyers—Lenin was less encouraging. Writing of the need to rule them “with an iron rod and

¹³ Jonathan Shapiro (Zapiro), *A mixed message from government*, SUNDAY TIMES, FEB. 24, 2002, available at <http://www.sundaytimes.co.za/2002/02/24/insight/zap.gif> (last visited Mar. 4, 2002).

¹⁴ See, e.g., National Executive Committee of the African National Congress, *Lend a Caring Hand of Hope*, available at <http://www.anc.org.za/anedocs/pr/2002/pr0320a.html> (last visited Mar. 27, 2002); But see Cabinet Statement on HIV/AIDS, Apr. 17, 2002, available at <http://www.gov.za/speeches/cabinet/aid02.htm> (last visited Apr. 18, 2002).

¹⁵ TAC v. Minister of Health, 2002 (4) BCLR 356 (T). See also Mitch Besser et al., *Interim Findings on the national PMTCT Pilot Sites: Lessons and Recommendations*, iv-v, at <http://www.hst.org.za/pubs/pmtct/pmtctinterim.htm> (last visited Mar. 4, 2002). A government commissioned study of its limited prevention of mother-to-child transmission (PMTCT) programme made the following recommendations:

Plans for expansion must therefore simultaneously address the systemic and infra-structural constraints in order to avoid a multiplication of poor and/or non-sustained service delivery, as well as to reduce levels of health care inequity. As with other services, the full potential of the PMTCT programme to reduce the number of HIV infected babies and improve overall health status will only be realized if the health system is capable of delivering the service optimally.... It would be more useful to highlight the potential of the PMTCT programme to act as an engine or catalyst for the improvement of the health system and of primary health care services in general.... Failing to conceptualize the PMTCT programme in this broader and catalytic role could represent a missed opportunity for the country, or even worse, result in the PMTCT programme undermining other essential areas of primary health care.

put them in a state of siege, for this intelligentsia scum often plays dirty,” his advice was simple: “It’s better to fear lawyers and not trust them”.¹⁶

In South Africa, however, our approach is somewhat different. Our fine tradition of public interest litigation illustrates how law may effectively be used in support of larger human rights struggles.¹⁷ “Because the [South African] regime used legal institutions to construct and administer apartheid”, Richard Abel explains, “it was vulnerable to legal contestation.”¹⁸ As E.P. Thompson notes, “[t]he essential precondition for the effectiveness of law, in its function as ideology, is that it shall display an independence from gross manipulation and shall seem to be just. It cannot seem to be so without upholding its own logic and criteria of equity; indeed, on occasion by actually being just.”¹⁹

Democratic South Africa is a fundamentally different place. While the distinguishing feature of public interest litigation in the apartheid era was the attempt to control the exercise of public power and thereby limit and reduce human rights violations, TAC’s use of the law in securing access to treatment is to ensure—rather than prevent—state action. But while TAC recognises that public interest litigation may be used as an important tool of social change, it also believes that the use of law should be limited and strategic, that the lawyer plays an important albeit limited role within a broader social movement, and that a comprehensive understanding of the political and economic context informs the manner in which the law is used to further the aims of the movement.

As a result, TAC’s approach to the use of law is multifaceted. While TAC aims to secure a legal victory whenever litigation is undertaken, the organisation is also highly aware of the role of the litigation process beyond the orders made in court judgments. In addition, by framing political and moral demands in the language of legal rights and constitutional obligations, TAC seeks to use the law without necessarily having to litigate. Recognising that the “formal content of a bill of rights is often less useful than the fact that it brings under scrutiny the justification of laws and decisions”,²⁰ Etienne Mureinik provides the basis for such an understanding:

¹⁶ See PLONOE SOBRANIE SOCHINENII (5th ed. 1958-1965), cited in Jane Burbank, *Lenin and the Law in Revolutionary Russia*, 54 SLAVIC REV. 23, 29-30 (1995).

¹⁷ See RICHARD L. ABEL, *POLITICS BY OTHER MEANS: LAW IN THE STRUGGLE AGAINST APARTHEID, 1980-1994* at X-XI (1995) (Forward by Geoffrey Budlender).

¹⁸ *Id.* at 3.

¹⁹ E.P. THOMPSON, *WHIGS AND HUNTERS: THE ORIGIN OF THE BLACK ACT 262-63* (1975).

²⁰ Etienne Mureinik, *Beyond a Charter of Luxuries: Economic Rights in the Constitution*, 8 S. AFR. J. HUM. RTS. 464, 471 (1992).

“[A]ny decisionmaker who is aware in advance of the risk of being required to justify a decision will always consider it more closely than if there were no risk. A decisionmaker alive to that risk is under pressure consciously to consider and meet all the objections, consciously to consider and thoughtfully to discard all the alternatives, to the decision contemplated. And if in court the government could not offer a plausible justification for the programme that it had chosen . . . then the programme would have to be struck down.... The knowledge that any government programme could be summoned into court for searching scrutiny would force its authors closely to articulate their reasons for dismissing the objections and the alternatives to the programme, and precisely to articulate the reasons that link evidence to decision, premises to conclusion. The need to articulate those reasons during decisionmaking would expose weaknesses in the programme that might force reconsideration long before the need arose for judicial challenge.”²¹

Litigation is also used to place issues on the agenda, both before the judge and in the court of public opinion. In the much-publicised case of *The Pharmaceutical Manufacturers’ Association of South Africa and Others v. The President of the Republic of South Africa and Others*,²² one of TAC’s primary objectives was to “turn a dry legal contest into a matter about human lives”, not only for the purpose of placing the impugned legislation in its proper context but also to influence public opinion.²³ Thus TAC’s founding affidavit was deposed to by the campaigns co-ordinator of the Congress of South African Trade Unions (COSATU),²⁴ South Africa’s largest trade union federation and a partner in the ruling African National Congress-led tripartite alliance government,²⁵ with supporting affidavits from people living with HIV/AIDS and doctors offering “personal testimony about living with HIV or AIDS in the shadow of medicines that are available but not affordable.”²⁶

²¹ *Id.* at 471-473.

²² See *The Pharmaceutical Manufacturers’ Association v. The President of the Republic of South Africa*, *supra* note 12.

²³ Mark Heywood, *Debunking ‘Conglomo-talk’: A Case Study of the Amicus Curiae as an Instrument for Advocacy, Investigation and Mobilisation* 12 (paper on file with author) (presented at *Health, Law and Human Rights: Exploring the Connections—An International Cross-Disciplinary Conference Honoring Jonathan M. Mann*, Philadelphia, PA, Sept. 29 – Oct. 1, 2001).

²⁴ Ms. Theo Steele, also an executive member of TAC.

²⁵ The third member of this alliance is the South African Communist Party.

²⁶ Heywood, *supra* note 23.

II. LITIGATION PRIORITIES FOR 2002

TAC's litigation strategy for this year is an integral part of its broader campaign for the development, adoption and implementation of a public sector national HIV/AIDS treatment plan. As part of this campaign, TAC is co-hosting a national HIV/AIDS treatment conference with COSATU in June, and is currently completing its research on the financial implications of a national treatment plan and the economic and social benefits of treating people living with HIV/AIDS with appropriate medicines.²⁷

TAC is focusing on three areas of litigation this year: the conclusion of the prevention of mother-to-child transmission of HIV (PMTCT) case, a complaint before the Competition Commission on excessive pricing of brand-name ARVs and refusals to grant voluntary licenses, and a constitutional challenge to the limited coverage for people with HIV/AIDS offered by the country's largest health care insurer. Together, these cases target the three identified obstacles to treatment—government, the brand-name pharmaceutical industry and the health care insurance industry. In so doing, TAC maintains its independence and ensures that its opposition to various government policies is based on the principle of identifying and challenging obstacles to treatment access wherever they exist, but that it is prepared to fight alongside government wherever and whenever they “do the right thing”. As TAC Chairperson Zackie Achmat described the relationship between his organisation and the government after the brand-name industry withdrew its case against government in April 2001: “Our alliance with the government is not over.... As in any marriage we are the foremost supporters when necessary and the staunchest critics when necessary.”²⁸

A. PREVENTION OF MOTHER-TO-CHILD TRANSMISSION OF HIV (PMTCT)

At its launch on 10 December 1998, TAC called for the introduction of a national PMTCT programme. Calling on government to

²⁷ The campaign for expanded access to antiretroviral therapy is based on the principles set out in the Bredell Consensus Statement, adopted at a conference hosted by TAC on 18-19 November 2001, Treatment Action Campaign, available at www.tac.org.za/Documents/Statements/bredell3.pdf (last visited Mar. 4, 2002).

²⁸ Nicol Degli Innocenti & David Pilling, *South Africa's Positive Force*, FT.COM, Apr. 20, 2001, available at <http://news.ft.com/ft/gx/cgi/ftc?pagename=View&c=Article&cid=FT300MG9SLC&live=true> (last visited May 7, 2002).

with a commitment in an affidavit filed before court that they “have always maintained that they intend to roll out the programme of making Nevirapine available at all public health facilities”.⁵¹ Despite the doublespeak of official discourse, and regardless of the outcome of the appeal, the rollout of a comprehensive national PMTCT programme is clearly on the cards.

B. REDUCING THE PRICES OF ESSENTIAL MEDICINES

In spite of the many price reductions on ARVs that occurred in 2001, these medicines remain exorbitantly priced and, therefore, unaffordable for sustained and widespread use in a developing country such as South Africa. Believing that generic competition in the market for essential medicines is central to the reduction of prices, TAC is examining various legal strategies to obtain compulsory licences on essential medicines, as well as beginning campaign and legal work for a drastic reduction in the prices of essential diagnostic tools needed for the management of HIV.

In October 2001, Cipla–Medpro (Pty) Ltd (Cipla) lodged a complaint with the South African Competition Commission alleging that certain brand-name pharmaceutical companies have abused their dominant positions in the market by engaging in excessive pricing of their products and entering into certain exclusionary licensing and/or agency arrangements, in violation of legal restrictions on vertical and horizontal market arrangements.⁵² In essence, Cipla wants to be granted compulsory licenses to import and market generic ARVs.⁵³ The branded versions of these drugs are currently under patent in South Africa, with compulsory licenses yet to be issued.

TAC has decided to intervene in the matter by placing its own complaint before the Competition Commission. With a focus on excessive pricing and refusals to grant licenses, TAC believes that its’ complaint will—at minimum—result in a thorough investigation of pricing practices. But a successful complaint could lead to a declaration that a brand-name company has engaged in prohibited excessive pricing and/or a refusal to grant licenses,

⁵¹ *Applicants’ Heads of Argument on Leave to Appeal and Application to Execute* ¶ 3.3, available at <http://www.tac.org.za/Documents/MTCTCourtCase/Head-mtct-1-march-2002.doc> (last visited May 6, 2002) (quote by Dr. Ayanda Ntsaluba, Director-General of Health, in his answering affidavit on behalf of the respondents in the application for leave to execute against part of the original order in the main case). See also Cabinet Statement on HIV/AIDs, *supra* note 14.

⁵² Cipla-Medpro (Pty) Ltd is a joint venture between Cipla Ltd, an Indian generic pharmaceutical company, and its South African partner, Medpro Pharmaceutica.

⁵³ AZT, 3TC, nevirapine and AZT/3TC.

as well as an order compelling such a company to lower the prices of the ARVs in question to non-excessive amounts and/or to grant licenses. In addition, a successful complaint could lead to the imposition of a substantial administrative penalty.⁵⁴

TAC has decided to pursue the competition law avenue at this stage for a number of reasons. First, the Competition Commission is already investigating the complaint submitted by Cipla. TAC is concerned that this investigation is taking place in the absence of a public campaign on the issue.

Of further concern is Cipla's failure to deal with broader issues of public interest. These shortcomings not only have the potential to limit the benefit of any successful challenge, but also serve to keep the matter out of the public domain. Without broader debate, there is every incentive for the brand-name companies to drag legal processes out for as long as possible, in the hope that Cipla may eventually settle on substantially less favourable terms than originally requested.⁵⁵ TAC's intervention will force such companies to reconsider any protracted legal action if they are to avoid the type of public relations disaster that accompanied the *Pharmaceutical Manufacturers' Association* case.⁵⁶

Second, as a regulator with broad powers of investigation, the Commission is able to conduct an independent investigation into drug pricing. As part of its work, the Commission will be asked to deal with the actual costs of research and development in its determination of whether the prices charged for ARVs bear a "reasonable relation" to their "economic value",⁵⁷ particularly in respect of those drugs that were developed using public funds.⁵⁸

⁵⁴ TAC will be arguing that competition law may be used to facilitate the market entry of generic competition.

⁵⁵ In addition, an unsuccessful complaint by Cipla might prevent TAC from launching a similar case at a later stage. Section 67(2) of the Competition Act, 89 of 1998, does not allow for the Competition Tribunal to hear a matter if it is against a firm "that has been a respondent in completed proceedings before the Tribunal under the same or another section of th[e] Act relating substantially to the same conduct." Competition Act 89, § 67(2) (1998).

⁵⁶ See *The Pharmaceutical Manufacturers' Association v. The President of the Republic of South Africa*, *supra* note 12.

⁵⁷ Section 1(1)(ix) of the Competition Act defines an excessive price as "a price for a good or service which –

(aa) bears no reasonable relation to the economic value of that good or service; and
(bb) is higher than the value referred to in subparagraph (aa)."

Competition Act 89, § 1(1)(ix).

⁵⁸ AZT, 3TC and AZT/3TC are such drugs. In addition, it is widely acknowledged that most HIV/AIDS research in the United States is federally sponsored, primarily by the National Institutes of Health. See, e.g. Kaiser Family Foundation, *HIV/AIDS Research: Successes Bring New Challenges—Issue Brief*, 2-3 (June 2000), at <http://www.kff.org/content/2000/1600/research.pdf> (last visited Mar. 28, 2002). See also, Consumer Project on Technology, *Additional notes on government role in the development of HIV/AIDS drugs*, available at <http://www.cptech.org/ip/health/aids/gov-role.html> (last visited Mar. 28, 2002).

Third, the “activist” nature of the newly adopted Competition Act provides opportunities that are absent under other regulatory schemes. In short, the legislation is not primarily concerned with the individual parties to a dispute, but rather with the broader social and economic implications of the alleged prohibited conduct.

Fourth, a significant part of the regulatory flexibility afforded by international law, in the form of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS),⁵⁹ is dependant upon whether a particular practice is determined to be anti-competitive. Article 31 of TRIPS, which deals with compulsory licensing and arguably offers the greatest potential for increasing access to essential medicines, ordinarily requires that the use of a compulsory license be “predominantly” for the supply of the domestic market. This requirement is waived when the license is issued to remedy an anti-competitive practice.

Finally, and perhaps most important, is the need to revive the public debate about patent abuse and profiteering. TAC is of the opinion that since the collapse of the *Pharmaceutical Manufacturers’ Association* case last year and in the face of price reductions, the campaign against the brand-name pharmaceutical industry has lacked focus. A thorough investigation by the independent Competition Commission into pricing has great potential for achieving these goals.

C. CHALLENGING THE HEALTHCARE INSURANCE INDUSTRY

One of TAC’s key demands for the year is full coverage of treatment for people with HIV/AIDS who utilise the private health sector. At present, the extent of coverage varies considerably, from virtually no coverage for HIV-related treatment to full coverage under the Parliamentary and Provincial Medical Aid Scheme, which provides health care insurance to members of Parliament and the provincial legislatures, judges and the President of South Africa.⁶⁰

Based on a report of complaints received by the AIDS Law Project regarding limited benefits offered by one of South Africa’s largest health care insurers, TAC has endorsed a proposal for legal action, and is considering joining the case. At issue is a very broad definition of HIV-related treatment, and the related practice of limited benefits for such treatment. The complaints that will form the basis of the action relate to

⁵⁹ Agreement on Trade-Related Aspects of Intellectual Property Rights, Dec. 14, 1993, RESULTS OF THE URUGUAY ROUND, 33 I.L.M. 81 (1994).

⁶⁰ See, e.g., *Aid for AIDS: schemes contracted to AFA*, at http://www.pbm.co.za/AfA_schemes.htm (last visited Mar. 28, 2002).