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Debunking 'Conglomo-talk': A case study of the *amicus curiae* as an instrument for advocacy, investigation and mobilisation[1]

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> The resolution of this court case only confirms our view that international markets, which play an increasingly important role in all our lives, have no inbuilt conscience. But governments and ordinary people acting collectively have a precious responsibility to make the huge companies that dominate the markets accountable for how they respond to the most critical issues of our times.[2]

1 INTRODUCTION

The relationship between law and social and political issues in South Africa has a long and rich history. Much of this history relates to the abuse of law and law-making to serve segregationist ends and the response of 'progressive' lawyers to this.[3] Between 1907 and 1908, Mahatma Gandhi tried to use defiance of the law, and his position as an admitted advocate, to resist racist legal reforms being planned by the colonial government (the so-called Black Act). Then in the 1950s and 1960s the African National Congress (ANC) engaged legal strategies to try to resist and justify defiance of unjust laws.[4] This culminated in 1964 when Nelson Mandela and his co-accused used their defence in the Rivonia Trial to debunk some of the main tenets of apartheid and as a platform for advocacy and much

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2 Media Statement, Dr Manto Tshabalala-Msimang, Minister of Health, 19th April 2001.

3 See Chanock, 2001; Corder, H (ed) 1998.

4 "[D]uring these years the legal arena itself became a kind of politics, crucial to the very survival of the anti-apartheid movement." Clingman 1998: 232.

of the international mobilisation against apartheid that took place during the 1970s, 1980s and 1990s.[5]

For a decade after the imprisonment of Mandela and most of the rest of the ANC's senior leadership, internal opposition that used the law to challenge apartheid shriveled, in tandem with the collapse of most political opposition. It never died entirely and a number of lawyers, amongst them post-apartheid South Africa's first Minister of Justice Dullah Omar, remained in South Africa in what Omar described as "very dark years" using the law routinely to defend "hundreds and hundreds of people over the years on charges of contravening Pass Laws or workers who were charged with having gone on strike." [6] However, in the dying days of apartheid, on the crest of an enormous social mobilisation revitalised by the industrial working class and urban youth, law was again used extensively this time to defend a new generation of detainees from arbitrary arrest and torture, as well as more boldly to challenge some of the fundamental tenets of apartheid law and practice, such as the Pass Laws and the Group Areas Act. One of the most significant developments during this period was the beginning of the use of law pro-actively to challenge injustices and to mobilise public opinion. Ironically, public impact litigation in the 1980s and early 1990s found ways to turn defence into attack and thereby to turn apartheid's own laws on itself, exploit loopholes, and turn into *de jure* legal decisions what had often been made *de facto* by political struggle.[7]

This tradition of pro-active use of law is the subject of this paper. It is linked to a perspective that – whilst not diminishing its core content and core value – imbibes law with extra legal purpose and potential. However, it differs from descriptions of law against apartheid in that it refers to the use of law in a different social and political environment. In South Africa today non-state actors, such as privately owned monopolies, are emerging as concurrent violators of human rights. There is increasing recognition that 'civil' rights, such as the rights to dignity and equality, are heavily dependent on the realisation of 'socio-economic' rights, such as access to health care services. This requires both a redistribution and equalisation of access to resources. However, in many spheres of life access to resources

5 Mandela's 'ideal for which I am prepared to die' statement from the dock at the close of the Rivonia trial became one of the great speeches defining black people's aspirations for equality. It is reprinted and quoted in numerous texts including Clingman 1998: 314-315.

6 Broun 2000: 237. Broun's interview with Dullah Omar reveals how, even in the most difficult of circumstances, law can be creatively used in the interests of the disempowered. For example, Omar describes how he used the rules of criminal procedure, which allow evidence to be admitted in mitigation of sentence, to bring to Robben Island wives and relatives of political prisoners as witnesses. 'So we were able to beat the system in many ways. That was very exciting.'

7 This link between law and struggle is the subject of Richard Abel's book, *Politics By Other Means: Law in the Struggle against Apartheid, 1980–1994*. In a foreword, Geoffrey Budlender, reflects on the important but inherently circumscribed role of law in relation to social change, by acknowledging that 'what breathed life into all successful legal work was a spirit of resistance and rejection of unjust rule." (xi).

is dependent on the co-operation of non-state actors, such as multinational companies, that are not governed by traditional human rights legisl[illegible] In this context international law, as much as national law, becom[illegible] subject of contestation.

This article focuses on the legal action brought by the Pharmaceutical Manufacturers' Association (PMA) to test the constitutionality of an amendment to South Africa's Medicines and Related Substances Control Act of 1965.[8] It traverses some of the history of a case rich in irony, insofar as the PMA utilised rights in a Constitution that is primarily intended to protect vulnerable people against vested interests. The irony was compounded when the Treatment Action Campaign (TAC) – a late joiner to the litigation – used the same rights-protections in the Constitution to turn the PMA's case against itself, eventually contributing to the cessation of the litigation by the PMA.

The TAC's appropriation of the PMA case illustrates how legal action can be used to catalyse both national and international political mobilisation. Interestingly, the case acquired international significance without even culminating in a judgment. It shows how the discipline demanded of litigators can provide impetus for legal and social investigation. It can assist with the uncovering of facts that contest – and undermine – arguments of powerful vested interests that consciously masquerade as objective 'truths' and 'rules' but whose origin often lies in political manipulation, power-broking and self-interest, rather than in reality or indeed in law.

At the heart of the PMA case is the manner in which international law can be appropriated and written by forces with no formal law-making power, and then imposed upon governments.[9] As well as how this can be reversed. How the TAC and its allies achieved this is important to unpack and understand, because it offers a key to defence against one of the major strategies of human rights violators in the 'new world order' – dressing rights-incursions in the language of rights-protection and using unlimited economic power to pursue legal strategies to consolidate this.

This is not a new strategy. Summarising some of the uses of law against apartheid Richard Abel cautioned;

> As a sword, however, law may be ornamental or two-edged. Many victories, legislative or judicial, are largely symbolic, difficult or impossible to implement in practice. And vested interests may be better situated to invoke rights, derived from the Constitution or natural law, in opposition to legislative or executive reforms . . .[10]

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8 A fuller account of the evolution of the legislation, conflicts during the drafting process, and their aftermath is found in Gray, Matsebula, Blaauw, Schneider, Gilson 2001.

9 According to Abbott 2000: "There is little mystery to the political economy of the TRIPS Agreement as it emerged from intergovernmental negotiations that took place from the late 1970s to the early 1990s. This was a producer/technology-owner driven agreement. OECD industry groups were in substantial measure able to avoid subjecting the negotiations and agreement to close public policy analysis. Developing countries were encouraged to adopt the agreement by trade incentives, and were threatened with severe sanctions for failing to do so."

10 *Abel* 1995: 11.

In a similar vein, in May 1997 Dullah Omar, then the Minister of Justice used the first conference of the South African Human Rights Commission (SAHRC) to warn:

> Because of the imbalances we have inherited, only a few people have the capacity to enjoy their rights and the danger we face is that the Bill [of Rights] will be the sole preserve of the rich and powerful.[11]

Public-impact litigation should evolve with changing socio-political circumstance. Thus, the TAC's intervention in the PMA case, rather than attempting to emasculate state power, aimed to assist the government to defend its right to pass legislation to fulfill its constitutional obligations to progressively realise rights of access to health care services. It represented a strategic intervention into circumstances where although the new democratic government has political power, a great deal of economic power remains in non-state hands, limiting the ability of the state to address scarcity in health.

The full history of the case, and the legal issues it traversed, is lengthy and complex. Therefore, scrutiny will begin with the point when the TAC began to seek admission as *amicus curiae* in January 2001. However, before this, it is necessary to first provide a context for the court drama.

2 DE-CONSTRUCTING APARTHEID: IMPROVING ACCESS TO HEALTH CARE SERVICES

Making health care more accessible to South Africa's poor is a constitutional duty facing the government. In section 27 the South African Constitution states:

> (1) Everyone has the right to have access to –
>
> (a) health care services, including reproductive health care;
>
> (b) . . .
>
> (2) The state must take reasonable legislative and other measures, within its available resources, to achieve the progressive realization of each of these rights.[12]

This is not an easy responsibility to fulfill. As with so many other spheres of life, the health system that the new South African government inherited in 1994 was racially divided and unequal. On the one hand there was/is a private health sector, composed of highly paid doctors and modern medical facilities. This sector serves 20% of the population (mostly white) – but accounts for 80% of national spending on health. On the other hand there is the public health sector, where 80% of the population seek care (mostly black) – but where only 20% of health expenditure takes place.

In South Africa, as well as in the rest of the world, systems of private and public health care operate along parallel lines. But they are not independent of each other. If private care is excessively expensive more

11 Quoted in Heywood and Cornell: 77.

12 Constitution of the Republic of South Africa Act 108 of 1996. In addition s 237 requires that "constitutional obligations ... be performed diligently and without delay" (s 237).

people are dependent on public hospitals. Similarly, if doctors and nurses are highly paid in the private sector, then health workers are sucked away from public facilities.[13] The Constitutional duty to improve access to health care services thus dictates not only that government invest in public health but also that it address distortions in the private sector. In essence, making public health care more accessible means making private health care more affordable and efficient.

The market for medicines in South Africa became grossly distorted under apartheid. A first-world regulatory authority oversaw the registration of medicines and guaranteed their safety and efficacy – but it had no control over prices.[14] The emergence of a substantial 'whites-only' private health sector, funded largely by medical insurance schemes, meant that medicine sold to this part of the market could be highly priced – and highly profitable. Even during the years of apartheid this was recognised to be a problem, particularly by health providers: several commissions were set up to investigate the barriers to wider use of quality generic medicines – but their recommendations for legal reforms to permit wider use of generic medicines were thwarted by the pharmaceutical industry.[15] For example, in 1984 the South African Pharmacy Board amended its ethical rules and *Government Notice R2525* gave pharmacists permission to substitute items on a medical prescription without the prior permission of the prescribing doctor. This was challenged in Court by the drug companies and the SA Pharmacy Board lost the case. Ten years later, in 1995, the South African Pharmacy Council repeated its support for generic substitution of brand name medicines on the grounds that it would "undoubtedly assist the community pharmacist to provide a more affordable pharmaceutical service to the public, thereby improving the accessibility of community pharmacy without compromising quality. . ." – a position that was supported by the Pharmaceutical Society of South Africa (PSSA).

The historic absence of regulation of medicine prices, and perverse practices that evolved in the dispensing and supply of medicines, permitted very high prices to be set for medicines sold by private doctors, clinics and hospitals.[16] This fuelled general medical inflation which reinforced barriers to wider access to private care.

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13 The 1998 SA Health Review (Health Systems Trust) reports that "most recent graduates are employed in the public sector, and 77% of all doctors who qualified in the previous five years are working in this sector. In contrast 10 years following qualification, the majority are working in the private sector" (p150).

14 The Medicines Control Council (MCC) was established in 1966, after the promulgation of the Medicines and Related Substances Control Act 101 of 1965.

15 The Snyman Commission, 1959–1962; The Steenkamp Commission, 1975–1978; The Browne Commission.

16 In the Answering Affidavit of the Director General, on behalf of the Minister of Health, the Amendment Act's introduction of a single exit price was justified on the grounds that whilst volume discounts were permitted on medicines "there is very little evidence that these are passed on to the consumer. This is because the current system allows the distributors, wholesalers and retailers to make a profit on medicines and appropriate these discounts into profits and not pass them on to the consumer". Answering Affidavit, Ntsaluba, para 14.1 (e), p. 190.

In the public sector most patented medicines were unaffordable. Further, generic medicines, although sold at prices greatly lower than to the private sector, were still sold at prices that the South African government would allege in its legal papers to be substantially above what was normal in many other countries.[17]

Racial discrimination in access to health care services was thus exacerbated by economic discrimination that favoured the wealthy. This situation was carried over into post-apartheid society and, some surveys suggest, has got worse. For example in 1999, 66% of people surveyed by the Community Agency for Social Enquiry (CASE) said "cost" was their main reason for not seeking health care when they were sick. In the same survey 40% of African respondents said that access to medicines had "got worse".[18]

Tackling these distortions and their consequences requires a variety of strategies. To this end a range of policies and laws have been introduced since 1994.[19] For example, one objective of government health policy is to try to make private hospital care more affordable and thereby reduce the patient-load and the resource drain on the public sector. Thus the Medical Schemes Amendment Act, No. 131 of 1998 aims to make private health care more widely available by removing unfair barriers to membership of medical schemes and strengthening the regulations governing the industry.[20]

Another area of focus was on the affordability and availability of medicines. A tight-rope had to be constructed requiring careful balance. A National Drug Policy was published in 1996. Its aim is to rationalise the prescription and use of medicines through a variety of mechanisms, including a pared down Essential Drug List (EDL). Several legal mechanisms to reduce the drugs bill were also suggested, including encouraging generic substitution of off-patent medicines, the use of parallel importation and possibly compulsory licensing.[21]

It was hoped that the combination of these strategies would reduce the costs incurred in the purchase (by the state) and the prescription (by the

17 Disputes about the price of medicines were a running sore between the PMA and the government even before this litigation commenced. See: Public Protector, Report No 6, "Report on the Propriety of the Conduct of Members of the Ministry and Department of Health Relating to Statements in Connection With the Prices of Medicines and the Utilisation of Generic Medicines in South Africa", November 1997.

18 The Second Kaiser Family Foundation *Survey of Health Care in South Africa*, Community Agency for Social Enquiry (CASE), August 1999.

19 These were first set out in the White Paper for the Transformation of the Health System in South Africa, Government Gazette 17910, 16 April 1997.

20 Under the Act schemes may not registered if they discriminate on grounds of 'state of health'. Prescribed Minimum Benefits (PMBs) were introduced to provide a floor for health care provision.

21 Parallel importation is the importation of a brand-name medicine under patent from a country where the patentee sells it at a lower price than in the local market. Compulsory licensing refers to the over-riding of certain patent rights by the licencing of a competitor to produce and market a medicine that is still under patent. Compulsory licensing, in a limited number of circumstances and according to legally defined processes is permissible under ss 4 and 56 (a) and (c) of the Patents Act, No. 57 of 1998.

public provider) of medicines. The objectives: lowering the state medicines bill – whilst increasing medicine availability; decreasing the amount spent on medicines by private providers – so as to increase affordability of private care; increasing the amount of money available for other health services whilst simultaneously increasing the volume and public health value of medicines.[22]

It was with these obligations in mind that, on 31 October 1997, the National Assembly passed the Medicines and Related Substances Control Amendment Act, No. 90 of 1997 (hereafter referred to as the Medicines Act).[23] This law amended the Medicines and Related Substances Control Act, No. 101 of 1965 and contained a range of measures that aimed to make medicines more affordable and improve the functioning of the Medicines Control Council (MCC).

The Act was fiercely opposed by the then Democratic Party (DP), New National Party (NNP) and representatives of the pharmaceutical industry. On 18 February 1998, the PMA and forty multinational drug companies filed a Notice of Motion and Founding Affidavit with the Pretoria High Court and sought an interim interdict to prohibit the President and Minister of Health from bringing into operation crucial sections of the Amendment Act, and declaring the sections unconstitutional. Many of the contested measures were already standard practice in developed countries and, *prima facie*, in compliance with international agreements such as that on Trade Related Aspects of Intellectual Property (TRIPS). In effect, the legal action was an attempt by the PMA to use the Constitution to annex additional powers and safe-guards for intellectual property that are not part of TRIPS; to fill in some of the ambiguities in TRIPS, particularly its vagueness around 'parallel importation'; and to warn other developing countries off a similar path.[24] The Act was thereby stopped in its tracks.

Between February 1998, when the PMA initiated legal action, and 10 November 2000, when it set the matter down for hearing in 2001, a great deal happened politically.[25] Although litigation had commenced, much of the substance of the dispute was thrashed out outside of the courts. For example, in 1998 pharmaceutical company lobbying was successful in having South Africa placed on the United States Trade Representatives' (USTR) 301 Watch List. A year later it was removed as a result of activist pressure, primarily in the United States, that led to then US President Bill Clinton signing an 'Executive Order' that recognised the rights of countries in Africa to pass legislation without interference from the United

22 In 1996 South Africa developed a National Drug Policy (NDP) with the co-operation of the pharmaceutical industry, where these objectives were set out.

23 The National Council of Provinces passed the Medicines Act on 20 November 1997 and President Mandela signed the law on 25 November 1997.

24 The pharmaceutical industry has been lobbying OECD governments to use the next round of world trade negotiations to strengthen TRIPS, or to create a "TRIPS-plus" agreement. These aims were thwarted by protests targeting the WTO meeting in Seattle in 1999 and will be more difficult in the wake of the global awareness that has developed around pricing policies amongst both governments and citizens.

25 This period is analysed in detail in Gray, Matsebula, Blaauw, Schneider, Gilson 2001. See also Bond 1999.

States, as long as it was TRIPS-compliant.[26] AIDS activism helped to catalyse an international activist movement that challenged the impact of international trade law on social and economic rights (such as health).

In South Africa, the froth in international politics masked a stasis around the court papers. The pharmaceutical companies benefited by this inertia. The Ministry of Health lacked the capacity to respond timeously to the PMA's papers and this led to requests for postponements by the State Attorney, which were readily agreed to. The consequence of these postponements was that measures which would have drastically brought down the price of many medicines (as well as their profitability) were delayed, saving the pharmaceutical companies many millions of dollars and delaying the advent of affordable health care in South Africa.[27]

This period had also seen the rapid emergence of an AIDS activist movement in South Africa with the launch of the TAC in December 1998. Between 1999 and 2001, the TAC was aware of the issues in the court case and frequently engaged the PMA through demonstrations with demands to withdraw the case.[28] However, a lack of capacity delayed the TAC's ability to tackle the issue squarely. Other campaigns were more aggressively pursued and alliances constructed. This helped prepare civil society in South Africa for the kind of mobilisation that would be required in the PMA matter.[29] In 2000, the TAC waged a campaign against Pfizer Inc. to demand a price-reduction of its anti-fungal medicine, Diflucan (fluconazole). The campaign reached a high-point in October 2000 when the TAC chairperson, Zackie Achmat, returned to South Africa from a trip to Thailand with 5000 tablets of a bio-equivalent generic fluconazole (Biozole) – and the TAC held a press conference to announce the commencement of its patent abuse defiance campaign. This action led to intense public discussion about the morality of patent abuse and pricing of medicines. It dominated the news headlines for a week, and led to television and radio discussions. Its effect was to educate the public and

26 A Press Release of 17 September 1999 from the Office of the USTR stated that the US and SA governments had "come to an understanding with respect to South Africa's urgent need to provide better, more affordable health care while ensuring that intellectual property rights are protected." The limitation of the Executive Order was that it confined itself to Africa, a problem that arguably emanated from the activist focus on the African AIDS epidemic to the exclusion of the needs of populations in other developing countries, particularly Asia and Latin America.

27 Speaking in his personal capacity, Dr Wilbert Bannenburg, estimated that the delay in the advent of mandatory generic substitution could have saved the pharmaceutical companies up to R2 million per day. According to Dr Bannenburg, based on an annual private sector turnover of R7 billion, of which up to 50% (R3,5 billion) are brand name medicines that fall into a 'substitutable target group', a savings of 10–20% on annual turnover was achieved by the industry by delaying the Act with litigation. This amounts to R350–700 million per year or R1–2 million per day. Personal correspondence, 29 November 2001.

28 A chronology of these actions was included in TAC's 1st March 2001 Replying Affidavit responding to PMA claims that it was an organisation that lacked "substance" and which had failed to approach the Court according to time-frames set out in the rules of Court.

29 See Lewis 2001 (video history) and an overview of the history of TAC, written by journalist Judith Soal, can be found at www.tac.org.za.

build sympathy and support for the TAC across the social and political spectrum.[30] The campaign undoubtedly influenced the decision of Pfizer to donate Diflucan for use in the public sector by people with certain AIDS-related opportunistic infections.

By early 2001 in the wake of successful advocacy to highlight the price differentials between essential generic and patented medicines, particularly fluconazole, the TAC was ready to intervene in the court case. On 10 November 2000, the PMA had quietly set the matter down for hearing in March 2001. Strangely, the South African government had not drawn public attention to this. This changed on January 11th 2000 when the PMA's Head of Scientific and Regulatory Affairs, Maureen Kirkman, informed the TAC of the dates. Early in January a discussion was held with senior lawyers about whether the TAC should aim to join as a party. The TAC was advised that this would seriously delay the hearing. Therefore, it was decided to seek permission from the parties and the court for leave to intervene as *amicus curiae*.[31]

The TAC's first objective was to break the two year inertia and to draw international attention to the dates of the case. This it did on January 16th at a press conference where the TAC announced that it would seek to join as *amicus curiae* and simultaneously mobilise an international campaign to call on the pharmaceutical companies to withdraw from the matter. Thereafter, these two strategies were pursued separately – but at all times in close parallel to each other. Each benefited the other.

2.1 Advocacy

In one important respect the TAC intervention in the PMA case differs from public impact law under apartheid. After the Soweto uprising in 1976 the social movement against apartheid revived independently of the law, but took advantage of the law and progressive lawyers to consolidate and catalyse change. After the political defeats of the early 1960s very few lawyers were prepared to take on apartheid in the absence of a political movement. Many went into exile or were imprisoned. Their courage returned with the return of political opposition. By contrast, although on an infinitely smaller scale at this stage, the TAC has used law and mobilisation

30 A cartoon in the *Cape Times* depicted the Minister of Health standing beside a bedridden person with AIDS, and two jars of medicines, one labelled 'Big Company AIDS Drugs $$$' and the other 'Cheap generic AIDS drugs courtesy of TAC' and saying "You can't have these because they're too expensive, and you can't have these because they're illegal. Now is there anything else I can help you with?" to which the person responds "Oh ja – I was wondering if it's just coincidence that 'Hippocratic and Hypocritical sound so similar?'"

31 According to Rule 16A of the Rules of Court leave to join as *amicus curiae* must be sought within 20 days of the "filing of the affidavit or pleadings in which the constitutional issue was first raised". However, this new rule was added in 2000 (GNR849 of 2000), long after the PMA case had commenced. One of the major tactical errors of the PMA was to base much of its strategy on withholding consent. This mistake allowed the TAC legitimately to present the PMA as wanting to keep the voice of affected people out of the hearing. It also became a strategic error in court, as the arguments made by the PMA's senior counsel became increasingly tenuous, and clearly irritating to the judge.

concurrently, and has often been responsible for both. It has been aided in this by a Constitution with a clear Bill of Rights, and a legal tradition that encourages the use of litigation as a way of colouring in and defining its principles.

There is also an important overlap between the two periods. The TAC draws much inspiration from the work of Edwin Cameron, one of the pioneers of public impact law in the 1980s. Senior Counsel for the TAC in the PMA case was Advocate Gilbert Marcus, who has had long involvement with public interest law and in 1985 argued as *amicus curiae* in a case that led to the unbanning of the Freedom Charter.

On 15 and 16 of January 2001 the TAC national executive committee (NEC) met in a clinic run by Medicins sans Frontieres (MSF) in Khayelitsha in Cape Town. Spirits and confidence were high, in the light of the importation of another batch of fluconazole tablets from Thailand (this time declared at customs by Morne Visser, a local TV actor), which were handed over to cheering activists at Cape Town International Airport in the glare of television cameras. The TAC knew that this was testing the legal boundaries of the exemption that it had received from the Medicines Control Council (MCC) in 2000 to import the generic medicine for use by a clinic in Cape Town. A resolution to try to intervene as *amicus curiae* was unanimously passed by the NEC[32] and the TAC called for a Global Day of Action against the pharmaceutical companies on March 5th 2001, the first day of the court case.[33] This call received significant attention from the local and international media.[34]

Between January and March mobilisation in South Africa and internationally was intense. The start of the court case was a focal point, but the legal process engaged in by the TAC to try to gain admission as *amicus curiae* gave it a day-to-day reality, and allowed the legal questions to be teased out into the public domain and to provide valuable public education around the issues.

On March 5th 5000 people, led by religious and trade union leaders, marched past the Pretoria High Court and handed a Memorandum over at the US Embassy. On March 4th COSATU and the TAC staged an all night

32 Paragraph 2 of the resolution read: "TAC's participation should ensure a speedy process to remedy the collusive paralysis between the parties that have prevented this court case from being completed with the urgency that it deserves. In the period of its delay and counter-delays, more than 400,000 people have died of AIDS related illnesses according to government."

33 On 19 January 2001, TAC issued the following call: "TAC calls on people in every country to mobilise against drug company profiteering on Monday 5 March 2001. On this day, the action by more than 40 multinational drug companies against the South African government will be heard in the Pretoria High Court. Millions of people will die from HIV/AIDS and other illnesses, if the drug companies succeed in their action. TAC specifically calls on our allies Médecins Sans Frontières, HealthGap Coalition, ACTSA and all the organisations who endorsed the Global March for HIV/AIDS Treatment Access to mobilise. A victory for the drug companies in this case will set back the struggle for access to essential medicines in all countries. TAC will mobilise actions against drug companies throughout the week 5–12 March 2001."

34 *Business Day*, 17 January 2001.

vigil in a tent outside the Court, and the TAC leaders seized the rare opportunity to workshop the most senior officials of COSATU until 2 in the morning on legal and political issues posed by the case.

Internationally the TAC formed alliances with Oxfam, MSF, Action for Southern Africa (ACTSA) in Britain and the Health-GAP coalition in the USA – several of these organisations were already campaigning against the pricing practices and abuse of patents by pharmaceutical companies. These allies were able to mount pressure directly against the companies as well as on the governments of industrialised countries. When the case began on March 5th, demonstrations were held in 30 cities world-wide, including in Brazil, the Philippines, the USA, Britain, Kenya, Thailand, France, Italy, Denmark, Australia, and Germany. By this point over 250 organisations from 35 countries had signed a petition opposing the legal action.[35] The civil society mobilisation, supported by international luminaries such as John Le Carre, left the companies increasingly isolated. After the postponement of the case on March 6th, MSF initiated an international petition which collected 250 000 signatures, and during this time played a crucial part in persuading the European Union and Dutch government to pass resolutions calling for the case to be dropped.

During this period the media made great play of the 'alliance' between the TAC and the government – an alliance that drew criticism from some quarters on the left. It is important, therefore, to note the tensions behind this mobilsation.

In reality there was little contact between the TAC and the government. On February 1st a TAC/ALP delegation had met with the Director General of the Health Department, Dr Ayanda Ntsaluba, and discussed the case. The TAC received a positive response to its request to join as *amicus curiae*, although Ntsaluba explained that the final government position would depend on consent from all the Respondents. This had to include the Office of the President, with whom the TAC has a very poor relationship, largely as a result of the President's destructive public flirtation with the 'AIDS dissidents' and their views. Thereafter there was no direct contact. Although the press were generally unable to grasp the point, the Ministry of Health understood that the *amicus curiae* intervention was but a stage in the TAC's campaign for treatment access, that would lay the foundations for intensified criticism of the government's policy concerning access to treatments for HIV.[36] Unlike COSATU, the African National

35 This petition was published as a full-page advertisement in *Business Day* on 8 March 2001.

36 Pat Sidley, an experienced South African journalist, was well-aware of this. In a column for *Business Day* (23/04/2001) titled "Court of Public Opinion" she wrote: "Alongside the pile of documents on my desk is a poster picked up at one of the TAC news conferences. It is a picture of GlaxoSmithKline's CEO in SA, John Kearney, and it reads: 'AIDS profiteer. Deadlier than the virus.' It infuriated and hurt him. Next to it is another TAC poster that carries – if you will – the writing on the wall. It pictures Trade and Industry Minister Alec Erwin. Under his name the message reads: 'Issue compulsory licences. Produce generic anti-retrovirals.' It points to the next target – and more lessons to be learned."

Congress (ANC) kept its distance from the TAC campaign. After victory had been secured the ANC excluded the TAC entirely from acknowledgement. A 'victory rally' held in Church Square in Pretoria on April 19th left out the TAC completely and tried to elevate organisations that had engaged very little with the case. Similarly, whilst the Minister of Health congratulated the TAC's international allies, such as Oxfam and ACTSA, she privately chided them for working with the TAC.[37]

Leaders of the ANC and some Ministers expressed concern that the TAC had hijacked the case and turned all attention onto the question of access to antiretroviral drugs. Whilst the media might have contributed to this impression, a study of what the TAC actually said and wrote will not support this.

The TAC's main arguments were that access to health is a human right that trumps rights to private property – particularly when these rights are being abused. Specifically, the TAC argued that patented antiretroviral medicines (needed by millions in Africa) bear out the main contentions of the Respondents: that patents were being used to gouge prices. Some of the measures in the Act, specifically section 15C, could be used to bring down prices of patented medicines. However, as important to the TAC's argument was the impact that section 22F (the requirement for generic substitution of off-patent medicines) would have on making medicines that treat and prevent opportunistic infections more affordable – as well as the potential benefits for the health system as a whole.

The mobilisation against the PMA and the other pharmaceutical company applicants was conscious and deliberate. Its success was not preordained. It came about as a result of creative advocacy, skilful interaction with the local and international media, and research. Critically important was the ability of the TAC and its international allies to win the arguments.[38]

2.2 The Treatment Action Campaign's approach to law

The PMA's attack on the Act revolved around a handful of key issues. But as is the fashion of legal action whose objective is to delay and frustrate legislation (and where resources are limitless), the papers attacked almost every clause of the Act, as well as the procedures by which it passed through parliament.[39] For an *amicus* applicant to be admitted, the *amicus* has to show that it can provide insight and argument that does not already

37 The only senior politician to mention TAC by name was Deputy-President, Jacob Zuma, who issued a statement that specifically commended TAC's role in the case.

38 On this Pat Sidley wrote: "For many journalists of my vintage, the activists were manna from heaven; they even invoked some nostalgia for the anti-apartheid struggle of old. They were always available, returned phone calls (most of them) and provided mountains of useful, interesting information. They were dealing with a series of complex medical and legal questions, and were always available to teach and explain. Pharmaceutical companies, evasive and secretive at the best of times, retreated further into their shells." (*Business Day* 23/04/2001).

39 Founding Affidavit, M Deeb, 18th February 1998.

exist in the court papers – that its input is not erroneous, vexatious or repetitive. Unless special permission is sought, the *amicus curiae* must confine itself to points of law and not introduce new evidence that might be disputed. [40] Departing from the thrust of the international campaign which had rallied mainly around a defence of section 15C of the Act, the TAC decided to focus on three key sections (including 15C) and to use the need for medicines created by the HIV/AIDS epidemic to highlight why each of these measures was necessary and justifiable.

The three areas were identified as sections 15C, 22F and 22G. They dealt with parallel importation, generic substitution and the establishment of a pricing committee.[41]

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40 For example, in *Hoffman v SAA* (2001 (1) SA (CC) appealing *Hoffman v SAA* (2000 (2) SA 628 (W)), the AIDS Law Project, which was admitted as *amicus*, sought special permission under 9(8) of the Constitutional Court Rules to introduce evidence from 'A' v SAA, Labour Court J 1916/99 on the grounds that it contained information that was "relevant to the determination of the issues" before the Court.

41 **15C. Measures to ensure supply of more affordable medicines**. 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 contained 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)."

22F. Generic substitution

(1) Subject to subsections (2), (3) and (4), a pharmacist shall –

(a) inform all members of the public who visit his or her pharmacy with a prescription for dispensing, of the benefits of the substitution for a branded medicine of an interchangeable multi-source medicine; and

(b) dispense an interchangeable multi-source medicine instead of the medicine prescribed by a medical practitioner, dentist, practitioner, nurse or other person registered under the Health Professions Act, 1974, unless expressly forbidden by the patient to do so.

(2) If a pharmacist is forbidden as contemplated in subsection (1) (b), that fact shall be noted by the pharmacist on the prescription.

(3) When an interchangeable multi-source medicine is dispensed by a pharmacist he or she shall note the brand name or where no such brand name exists, the name of the manufacturer of that interchangeable multi-source medicine in the prescription book.

(4) A pharmacist shall not sell an interchangeable multi-source medicine –

(a) if the person prescribing the medicine has written in his or her own hand on the prescription the words 'no substitution next to the item prescribed;

(b) if the retail price of the interchangeable multi-source medicine is higher than that of the prescribed medicine; or

(c) where the product has been declared not substitutable by the council.

[continued on next page]

On January 26th 2001 letters were sent to the Applicants and the Respondents, seeking their consent for the TAC to act as *amicus curiae*.[42] The TAC offered not to "burden the Court . . . with additional evidence" and only to use "uncontroversial scientific facts pertaining to the HIV/AIDS epidemic and the role of medicines in the management of this epidemic. . ."[43] This offer formed part of the TAC's legal strategy which anticipated that neither party would dispute published epidemiological reports about the HIV epidemic, and that the companies were unlikely to question the efficacy of their products. If undisputed, these two admissions would help to build a legal argument to justify the contested sections of the Act.

For the TAC limiting the *amicus'* interest to three key provisions of the Act also helped with public education about the issues – and forced the PMA to move into its terrain.

The response of the attorneys for the PMA might, arguably, have been the turning point in the case, or the point at which the pharmaceutical companies began to lose control over its direction. Consent was withheld on a number of technical and substantive grounds. The TAC was advised to "reconsider, and thereupon abandon, [its] intended participation in the hearing of this matter" and "thereby avoid the expenditure of resources which could be better applied elsewhere." According to the PMA's attorney:

> The issues before the Court .. are of a constitutional nature and do not relate, in any way, particularly to access to Aids medication. The submissions which the TAC wish to advance, . . . , do not differ from the submissions of the other parties to the application. No issues specific to the interests presented by the TAC and not equally applicable to other incurable diseases arise for decision in the application.[44]

22G. Pricing Commitee

(1) The Minister shall appoint such persons as he or she may deem fit to be members of a committee to be known as the pricing committee.

(2) The Minister may, on the recommendation of the pricing committee, make regulations –

(a) on the introduction of a transparent pricing system for all medicines and Scheduled substances sold in the Republic;

(b) on an appropriate dispensing fee to be charged by a pharmacist or by a person licensed in terms of section 22C (1) (a).

(3) (a) The transparent pricing system contemplated in subsection (2) (a) shall include a single exit price which shall be published as prescribed, and such price shall be the only price at which manufacturers shall sell medicines and Scheduled substances to any person other than the State.

(b) No pharmacist or person licensed in terms of section 22C (1) shall sell a medicine at a price greater than the price contemplated in paragraph (a).

(c) Paragraph (b) shall not be construed as preventing a pharmacist or person licensed in terms of this Act to charge a dispensing fee as contemplated in subsection (2) (b).

(4) The members of the pricing committee who are not in the full-time employment of the State may be paid such remuneration and allowances as the Minister, with the concurrence of the Minister of Finance, may determine.

42 The TAC's legal team at the AIDS Law Project included attorneys Anita Kleinsmidt, Teboho Motebele and Advocate Liesl Gerntholtz. Counsel for the TAC were Matthew Chaskalson and Gilbert Marcus, SC. Outside of the formal team the TAC benefited from the advice of Daniel Alexandra QC and Jonathan Berger.

43 Ms A Kleinsmidt, ALP attorney, letter to State Attorney, 26 January 2001, paragraph 7.

44 Letter from N J Vermaak, D M Kisch inc. dated 6 February 2001.

This response set parameters for the core arguments that would be made in the TAC's legal papers, as well as in its advocacy. If the PMA's contentions could be disproved, it also created the unique angle needed to justify admission as *amicus curiae*. The challenge was to show (a) how the measures in the Act *did* have bearing on AIDS medicines and (b) how the constitutional questions were not limited to those being posed by the PMA. Neither challenge was too difficult. The TAC was also assisted when on 14th February 2001 the State Attorney wrote that "our clients have consented . . ."

Before looking at substantive legal arguments, it is important to draw attention to the manner in which, from the outset, the *amicus* application functioned simultaneously as legal argument and advocacy tool.[45]

One of the TAC's objectives was to turn a dry legal contest into a matter about human lives – this was important for education of the court, as well as for public opinion. Thus, the TAC's main affidavits were deposed to by Ms Theodora Steele, the Campaigns Co-ordinator of South Africa's largest trade union federation, the Congress of South African Trade Unions (COSATU), which has nearly two million members. This served two purposes: it made an ordinary person, with real interests in the legislation, the deponent, and it gave COSATU a sense of ownership in the court battle. The ability to mobilise thousands of people depended very heavily on the close support of COSATU.

Similarly, reviving a tradition exploited by lawyers under apartheid of utilising affidavits as legally sanctioned instruments to tell the stories of lives affected by apartheid,[46] twelve poignant affidavits were collected from people living with or affected by HIV[47], two from doctors treating people with HIV[48], and one from the Head of Mission of Medicins Sans Frontieres (MSF) in South Africa.[49] These affidavits offered personal testimony about living with HIV or AIDS in the shadow of medicines that are available but not affordable. They were all attached as annexures to the Founding Affidavit.

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45 This was not a new strategy either in South Africa or elsewhere, but it was a strategy with innovations. For example, assisted by the communications revolution that has taken place since the end of apartheid, TAC ensured that within hours of being served on the parties and filed, all of its legal papers were placed on the TAC web-site where they could be accessed by journalists and activists alike. Unfortunately, despite the availability of legal papers, journalists across the world continued to misunderstand the nature of TAC's intervention and the Act itself.

46 Marcus 2001. In his paper Marcus describes how a test case opposing the forced 'resettlement' policy of the apartheid government (the *Magopa* case) enabled lawyers to "present to the world at large an extraordinarily moving picture of the history of the community spanning close to a century. That history was presented due to intensive field work done by Aninka Claassen who literally spent weeks living with the community and learning their history. In that way, the plight of the community was presented in an accessible form to the world ... The case attracted international attention and the outcry which followed the removal effectively brought an end to forced removals."

47 Mr Zackie Achmat; Ms Nomfundo Dubula; Ms Mkhanyiseli Mpalali; Ms Siphokazi Mthathi; Ms Helen Makebesana; Ms Ntombozuko Khwaza; Ms Thandeka Mantshi; Ms Rose Peni; Ms Patricia Dove; Mr Vernon Ogle; Ms Charlotte Mohapi; Ms Judith Ogle.

48 Dr Leon Geffen and Dr Herman "Themba" Reuter.

49 Dr Eric Goemaere.

The TAC's Founding Affidavit was filed on February 16th 2001. It aimed to establish that the AIDS epidemic *did* create an emergency in which the need for more affordable medicines is a matter of life and death for millions of people.[50] Even if the Act had not been devised with the AIDS epidemic specifically in mind (which it had not: its objective was to make *all* medicines more affordable) the epidemic created urgency and justification for legal measures to make medicines more affordable.[51] Contrary to what was suggested in Vermaak's letter the number of people with HIV, and the excessive price of HIV-related medicines meant that the *amicus did* have issues to raise that were not "equally applicable to other incurable diseases."[52]

The architecture of the TAC's Founding Affidavit is worth describing. An expert affidavit from a specialist HIV clinician, describing a range of the medicines that are used to fight HIV or its symptoms, was annexed in order to subtly challenge the applicants to dispute the efficacy of their products (which of course they did not).[53] With the safety and efficacy of the medicines and the scale of the HIV epidemic placed beyond the realm of dispute, it would be possible to concentrate the court's attention on how the *price* of medicines was the major barrier to access, and thus the *justification* for the measures in the Act, should it be found that they did limit the rights to property of the pharmaceutical companies.

A Founding Affidavit is intended to convey evidence, rather than legal argument – which is saved (under South Africa law) for presentation in 'Heads of Argument' (submitted shortly before the hearing) and in oral argument on the papers before the Court. However, the Founding Affidavit must, obviously, lay the evidentiary foundations for the legal argument.

The TAC's legal argument was that none of the three contested clauses was unconstitutional. Indeed, the TAC argued that they were dictated by a positive duty on the government to "progressively realise" rights of access to health care services and to protect rights such as dignity,[54] life,[55] equality[56] and the duty to act in the best interests of the child[57] – rights which

50 Stress was placed on the emergency caused by the HIV/AIDS epidemic in order to prepare for legal arguments that any limitation of property rights could be justified on the grounds that it was for a "public purpose or in the public interest" [SA Constitution, s 25(2)(a)], as well as in keeping with the TRIPS agreement which allows for expropriation (in the form of compulsory licensing) "in the case of a national emergency or other circumstances of extreme urgency" [TRIPS, Article 31, (f)].

51 The TAC Founding Affidavit stated at para 80: "Generic substitution will benefit all members of the public who rely on private sector care. However, people with HIV/AIDS who need treatment for opportunistic infections ... will benefit directly through accessing lower cost, good quality generics."

52 To establish this point the *amicus* annexed South Africa's 1999 and 2000 ante-natal survey, reporting an estimated 4,7 million HIV infections, as well as a December 1999 speech by UN Secretary General Kofi Annan at the launch of the International Partnership Against AIDS in Africa.

53 Expert Affidavit of Dr David Johnson.

54 Constitution on the Republic of South Africa, s10.

55 Ibid, s 11.

56 Ibid, s 9.

57 Ibid, s 28.

are dependent on measures to improve socio-economic conditions.[58] Poor people, the TAC alleged, were:

> directly dependent on the State's ability to fulfill its constitutional duty to bring about the progressive realisation of their rights of access to health care services. (FA, paragraph 13)

However, in view of its limited resources, large epidemics such as HIV and TB, and the high price of medicines generally:

> the South African Government is constrained in its efforts to provide adequate and good quality treatment for its citizens who are dependent on government hospitals and clinics . . . (FA, paragraph 54, quoting from a 'Memorandum of Agreement between the South African government and Pfizer Laboratories ltd', 1 December 2000)

The law is an attempt to overcome these constraints. The TAC argued that it was not a violation of TRIPS, pointing out that measures such as mandatory or incentivised generic substitution of off-patent medicines are common practice in industrialised countries. In the event that aspects of the Act might be found to be unconstitutional, the TAC argued that under South Africa's Constitution certain rights may be limited as long as the infringements are "reasonable and justifiable in an open and democratic society based on human dignity, equality and freedom".[59] The TAC argued that should any of the Act's measures be found to limit property rights, these could be justified on the grounds of the government's obligations to improve access to health care services, as well as other duties arising from international treaties:

> The government of South Africa is justified in seeking to avoid the massive social and economic disruption caused by the HIV epidemic – and other causes of illness – by limiting the rights of the patent-holders to make excessive profits from the sale of the drugs in South Africa. (FA, para 71)

Finally the TAC provocatively attacked one of the main tenets of the PMA's legal and media case: that the Act was a violation of intellectual property rights that would rob private investors of just rewards for invention and research, and thereby undermine preconditions for future research into disease and medicine.

> The research and development costs borne by the applicants have been recouped many times over. The *Amicus* Applicant has on a number of occasions challenged, for example, Glaxo Wellcome, one of the applicants, and Pfizer, a member of the First Applicant to state what its R&D costs are in relation to antiretroviral and other drugs. The information was never provided. (FA, para 83)

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58 In this line of argument TAC can claim support of the President of the Constitutional Court "... how can there be dignity in a life lived without access to housing, health care, food, water or in the case of persons unable to support themselves, without appropriate assistance? But social and economic policies are pre-eminently policy matters that are the concern of government. In formulating such policies the government has to consider not only the rights of individuals to live with dignity, but also the general interests of the community concerning the application of resources. Individualised justice may have to give way here to the general interests of the community." See Chaskalson 2000.

59 S 36 of the Constitution deals with Limitation of Rights.

The Founding Affidavit listed a number of medicines essential for the treatment of HIV and its opportunistic infections, and tempted the PMA bear to come out of its lair and do battle on where they originated from, and how much public and private money was invested in them. They did just that.[60]

2.3 Proceedings in Court

The TAC's Founding Affidavit, together with the mobilisation described above, shifted the core of the case irreversibly into territory the PMA were anxious to avoid. Retrospectively it is clear that the PMA's legal advisers erred in seeking to deny the TAC the right to be *amicus curiae* on legal technicalities.[61] This was evidenced by the approach adopted by Myreana Deeb, the CEO and main deponent on behalf of the PMA, whose Answering Affidavit replied to the TAC's submissions on the legal basis for cheaper medicines in the following way:

> 23.1 ... The question of whether medicines specific to treatment of HIV/AIDS related diseases are "expensive" or "cheap" or can and should be less expensive, also does not arise for decision in the main application.
>
> 23.2 The present application is not concerned with the determination of priorities by the State, the role to be played by the State in addressing the AIDS epidemic in South Africa, or by the impact of socio-economic realities on the healthcare system. The Honourable Court will also not be asked to determine the identity of those responsible for the research and development of specific medicines ... whether research was funded by individual companies or by foreign government agencies is wholly irrelevant to the main application.

On March 5th and 6th 2001, Deeb's assertions were vigorously interrogated and then rejected by the Court. In the space of a few hours Advocate Fanie Cilliers, Senior Counsel for the PMA, moved from arguing that the TAC had 'nothing new to bring to the court', to claiming that the argument of 'justification' was entirely new and that a 'minimum of four months' would be required to give the applicants 'a fair opportunity to put up evidence to reply to argument about justification.' Judge Ngoepe was unconvinced, stating at one point that 'this is a matter of public importance – not just the Respondents but people all over the world want a conclusion.' On March 6th he ruled:

> I am aware that the entire nation is interested and many people beyond our boundaries. ... I have considered the submissions and come to the conclusion that, given the importance and fact that an order may have implications to

60 This is not a new legal strategy, and again parallels can be found in the use of law under apartheid. In his biography of Bram Fischer, Stephen Clingman described how, despite the focus of historians on the political ethos surrounding the Treason trial "the essential drama ... was a legal one. ... the initial brilliance of the defence was that in all their harrying, pestering and baiting, they succeeded in shaping a case they knew they could win." See Clingman 1998.

61 These included challenging TAC to prove that it was an "organisation of substance", demanding TAC's constitution and questioning the medical credentials of Dr Eric Goemare, the head of mission of MSF in South Africa, to prescribe medicine in South Africa.

> every citizen in this country, I therefore rule that the TAC be admitted as *amicus curiae*. I also rule that the TAC is restricted to base and argue its case on the affidavit delivered with its Notice of Motion, subject to the right to reply.[62]

The PMA was given until March 28th (three weeks) to answer the *amicus curiae*'s Founding Affidavit. Thereafter, the Respondents and *amicus* were given until April 10th to respond to the Applicants. The matter was postponed until April 18th. The TAC's campaign to debunk and defeat 'conglomo-talk' now entered a new phase; perhaps best described as one of intensive research and investigation to refute the predictable response of the PMA. Further success now depended on the ability to marshal national and international research expertise into a final affidavit – in just over a month.

2.4 Investigation: Replying to the PMA's Answering Affidavit

On March 7th a legal strategy meeting was convened with the TAC's lawyers, the ALP, MSF and James Love, director of the Consumer Project on Technology (CPT). Immediately after this the TAC began to contact experts to depose supporting affidavits that would confirm and illustrate the main theses in the TAC Founding Affidavit and contradict the PMA's anticipated reply. Amongst those who agreed were Professor Andy Gray, a lecturer in pharmacology at the University of Durban Westville; Alex van den Heever, a health economist working with the Council for Medical Schemes; Prof Coleen Flood, a lecturer in law at the University of Toronto in Canada; Carmen Perez from Medicins sans Frontieres, and James Love. Discussions were also entered into with the Brazilian and Phillipine governments to try to persuade them to depose affidavits dealing with state practice in their countries. Areas for research and the collection of further evidence were also identified.

When it came, the PMA's Answering Affidavit was indeed predictable – and once again careless. Its arguments were clumsy and, given the resources available to the PMA, surprisingly poorly supported. An affidavit of 52 pages, deposed to by Deeb, was supported by annexures of 500 pages, mainly made up of pamphlets produced by the International Federation of Pharmaceutical Manufacturers Associations (IFPMA) – described by one TAC member as 'the collected works of Harvey Bale' (the Director of the IFPMA). Bale could hardly be described as an independent expert.

Essentially the PMA grouped its reply into four major themes. The PMA's first argument was that the extent of poverty in South Africa means that for millions of people *any* price for medicine is unaffordable: "this consideration is relevant to an argument relating to the state supplying medicines free of charge to such people and funding the cost thereof from general taxation." Oddly, Deeb thus deduced that this was "the only context, in which the constitutional obligations of the state (Section 7(2) of the Constitution) are relevant."[63] In a related jump in logic Deeb then

62 Personal notes taken in Court (not the official Court record).
63 Deeb, 28th March, Replying Affidavit, 4.1.

alleged that the TAC's arguments to justify measures such as generic substitution that would *lower* prices would benefit only a minority of people with HIV/AIDS who could afford to purchase medicine and use private sector health care (ie. people who were not the state's responsibility). This latter category was estimated by Deeb to be in the region of 0.84 million – too 'small a number' of potential beneficiaries to be justification for far-reaching infringements on intellectual property rights.

> . . . the real figure of patients with HIV/AIDS actually seeking or receiving medical treatment in the private sector probably stands at well below 1% of the population. The justification argument thus reduces to a relatively small sector servicing patients in the group that can best afford medicine, and to part of the sector in which the applicants need to recoup expenses and make profits (inter alia to enable them to continue to cross-subsidise the cheap medicines supplied to the public sector).[64]

The TAC's response to this was to point to the inter-connectedness of the private and public health services, how the policies of one impact directly upon another, and how many people who are poor seek care from both sectors.[65] Sister Susan Roberts, an infectious diseases sister at a Johannesburg hospital, provided an affidavit describing her experiences of the cross-over between the public and private sectors in a major tertiary hospital. She explained how when a hospital pharmacy "does not have the prescribed medicine available (ie. because the medicine is not on the essential drug list usually because of cost)" patients are given a prescription to be taken to a private chemist. In a particularly damning comment she reflected on how:

> In my opinion, decisions on what medicine to prescribe are sometimes made that are not in the best interests of the patient because of budgetary constraints that might face the hospital and the patient. (Roberts, 15)

The second PMA argument repeated tired assertions about the role of private investment in research and development (R&D), and the need to encourage and protect this investment through patent protection:

> If no encouragement in terms of reasonable financial returns on the required investment is to be allowed to the research-based multi-national pharmaceutical industry, the motivation for the search for a solution for this disease will disappear. Then the only remaining scenario is that the disease will find its own end: the funeral of the very last carrier of the virus. (7.2.1.4)

Here the TAC relied heavily on the expert evidence of James Love, which detailed the real costs of research into new medicines; how these are shared by governments and the private sector; and the profitability of the pharmaceutical industry.[66] As a result of an important collaborative investigation with students at the Universities of Minessota and Yale, the TAC was also able to describe how the compounds for two important anti-retroviral

64 Ibid, 4.2.5 (d).

65 Affidavits of van den Heever, Gray and Roberts (see www.tac.org.za).

66 GlaxoSmithKline's 'Preliminary Announcement of Results for 2000' was annexed, as was a report by reputable US consumer group, Public Citizen, dealing with the profitability of the industry.

drugs, d4T and abacavir, were discovered and developed with public funds at these universities and later licensed to Bristol Meyers Squibb and Burroughs Wellcome respectively.[67]

The third PMA argument was that, if the TAC's interest was with AIDS drugs, the legislation and thus the *amicus* was unnecessary because price discounts on medicines had been offered to the South African government. The PMA's Affidavit then proceeded to detail and annex correspondence concerning all the offers that had been made. By doing this, the PMA called the SA government's bluff, in so far as the government had repeatedly denied that any concrete offers had been made. But in doing so it publicised, for the first time, what prices were being offered as well as the nature of those offers.[68]

Although of little assistance to the PMA's legal argument (the TAC pointed out that charity did not "do away with the need for national legislation that aims to ensure all citizens sustainable access to essential medicines"[69]), this information was extremely valuable to the TAC, and to the cause of treatment access in South Africa. It provided a new platform for advocacy – and was one of the most tangible gains of the litigation. After the conclusion of the case the TAC called for the price reductions to be extended to the private health sector, and launched a campaign to this effect targeted at Bristol Meyers Squibb. After some half-hearted excuses about why this was not possible the prices were lowered across the board. Effectively, within the period of the TAC intervention the cost of triple-combination antiretroviral therapy in South Africa was reduced from approximately R3,000 per month to R1,500 per month. Although still way beyond the affordability of most people this holds out the prospect of a significant expansion of drug access in South Africa.

Finally, the PMA used its affidavit to re-state its claim that the legislation made the South African government a pariah state. Listing 150 countries that were co-signatories to TRIPS with South Africa (including Zimbabwe, Columbia, the United Arab Emirates, Pakistan, Brunei), and insisting that "most of these countries are open and democratic societies based on human dignity, equality and freedom" it claimed that "it will not be possible for the *amicus* to point to one other such country from the list cited above of which the legislature has passed legislation which. . .

9.1.14.5.1 Provides for the notion of exhaustion of patent rights, or for the permissibility of parallel importation in the terms utilised in section 15C and 1(4) of the 1997 Act;

9.1.14.5.2 Provides for generic substitution of prescribed medicine in terms of the mandatory terms (sic) and with the lack of administrative prescription found in the wording of section 22F of the 1997 Act; and/or

9.1.14.5.3 Provides for pharmaceutical cost containment in the manner and fashion as set out in section 22G of the 1997 Act:

South Africa stands alone."

67 TAC Replying Affidavit (Steele), paragraphs 36, 36.1 & 36.2.

68 An internal Memorandum of the TAC detailing the price reductions is provided as annexure C.

69 Steele, para 63 (c).

This was not a difficult challenge to rise to. The TAC was able to annex affidavits by two experts describing the practice of generic substitution in many other countries (including the USA) as well as to provide information about the legal approach to medicine price control in the United States, United Kingdom, Canada, Brazil and the Philippines. Direct discussions were entered into with the Philippine government and, had the PMA not withdrawn the case, the TAC was preparing to put into the record an affidavit from the former Secretary of Health, Dr Alberto G Romualdez, explaining Administrative Order 85, a regulation used by the government of the Philippines to parallel import medicines from India.[70]

The TAC's Heads of Argument, drafted by Advocates Matthew Chaskalson and Gilbert Marcus, SC, were filed on 17th April 2001. If the Replying Affidavit made rubbish of many of the 'factual' assertions of the PMA, the legal argument removed all vestiges of reasonableness concerning their allegations of rights violations. The TAC's legal team identified what they described as 'a weakness that lies at the heart of much of the applicants' case.' This was the manner in which the PMA depended upon an argument that the measures lacked rationality because they were 'over-broad', 'ambiguous' and 'over-shot the mark.' The TAC replied that a rationality review requires only "that the legislation has a purpose that is not unconstitutional and that it is rational to believe that the legislation will advance this purpose."[71] For example, section 217 of the Constitution requires that when an organ of state contracts for goods or services "it must do so in accordance with a system that is fair, equitable, transparent, *competitive and cost-effective*." This, the TAC argued, was relevant because:

> the capacity of the State to meet all of its constitutional obligations is ultimately dependent on the revenue it generates and the extent of its costs. Hence, the price at which medicines are purchased is a crucial determinant in the capacity of the State to meet its obligations, *inter alia*, to provide access to health care services.[72]

The TAC's legal argument was that the measures contemplated by sections 15C, 22F & G, were rationally related to the 'positive duty' on the state to protect and promote life[73] and dignity,[74] and to improve access to health care services. Put another way, "if the state were to stand by when efficacious drugs for the treatment of HIV/AIDS and associated infections are placed beyond the reach of most people in this country, it would ignore a profound threat to the lives of millions of South Africans . . ."[75]

The Heads of Argument also pointed out that the rights the PMA claimed to have been violated were 'for the most part':

> fundamental rights which are afforded the weakest level of protection in the Bill of Rights. Sections 9(1), 22 and 25(1) are enforceable only by rationality review

70 Ibid, paragraphs 41-56.
71 AC, Heads of Argument, para 4.6.
72 Ibid, 2.15.5.
73 Ibid, 3.14 - 3.17.
74 Ibid, 3.18 - 3.24.
75 Ibid, 3.31.

and therefore offer the applicants no more protection than the general rationality review they can invoke under section 1(c).[76]

On section 15C (parallel importation), the Heads adopted a slightly different approach, again indicative of the political and legal independence of the TAC from the government. From the outset, the TAC (and privately many others) had recognised that 15C's weakness was its imprecise formulation. Therefore, on March 6th Advocate Chaskalson, counsel for the TAC, had informed the judge that should the defence of the rationality of this clause be unsuccessful, the TAC would not mount an argument of "justification".[77] Initially this caused some shock with the government – who perceived that the TAC was surrendering one of the most important parts of the Act. However, the proposals made in the final Heads of Argument made it clear that this was not the case. The TAC stoutly defended the rationality of 15C but offered that, should the Court decide otherwise, there were less drastic alternatives than striking the whole paragraph down. "Three remedial possibilities present themselves:

9.6.1 First, section 15C may be subject to actual severance by deleting subparagraph (a).

9.6.2 Second, section 15C(a) may be subject to notional severance along the following lines:

Section 15C(a) is declared unconstitutional to the extent that the words "notwithstanding anything to the contrary contained in the Patents Act, 1978" shall not be construed to permit any derogation from the Patents Act other than parallel importation.

9.6.3 Third, words may be read into section 15C(a) along the following lines: "Notwithstanding anything to the contrary contained in the Patents Act, 1978, dealing with parallel importation . . .

Sadly, these arguments were never heard in open court.

3 WHAT WAS ACHIEVED?

Faced with this array of evidentiary, legal and public opposition, a number of member companies of the PMA balked. Unlike Macbeth who recognised that he was "in blood stepped in so far that, should I wade no more, returning were as tedious as go o'er" and chose to go on with his rampage, it seems the PMA realised that continuing could only worsen their situation – and that there was a way back.

The case resumed on April 18th amid rumours that members of the PMA were divided and that some of the larger companies were determined to withdraw and settle.[78] This seemed to be confirmed by the

76 Ibid. para 4.8.

77 TAC. First Heads of Argument, 5th March 2001.

78 The *Sunday Times*, April 2001, reported that UN Secretary General, Kofi Annan, had phoned President Mbeki and told him that "he had five of the biggest drug companies in the world knocking on his door, asking him to help them untangle themselves from a three-year court battle with the SA government ... The case had been deeply damaging to the pharmaceutical industry, casting it in the role of evil empire trying to thwart the Third World's efforts to get affordable medicines."

appearance of an additional legal team in court on behalf of some PMA members. An immediate request for an adjournment was made by the PMA. Then, on April 19th 2001, after 24 hours of intensive negotiations between pharmaceutical companies, who were split on the issue of abandoning the case, the PMA's legal team announced to Judge Ngoepe that its clients were unconditionally withdrawing their case against the government and that all costs (except those of the *amicus*) would be borne by the applicants.

The packed court erupted into spontaneous applause, again reminiscent of the conclusion of political trials in the 1980's. As activists celebrated, sang and toyi-toyied in the court room, the PMA and its legal team quietly left the room.

However, within a matter of hours, various observers and organisations were beginning to question what concretely had been achieved in compelling the PMA to withdraw. Skeptics of the 'victory' pointed to the fact that the PMA withdrawal meant that there would be no binding legal precedent in the form of a judgment. Others correctly pointed to the government's defence of section 15(C) in its Heads of Argument, as a mechanism solely for use for parallel importation of medicines:

> It is not the [Government's] intention to render nugatory the patent and other intellectual rights of the Applicants, but rather to activate the principle of exhaustion by importing more affordable genuine medicines placed by the Applicants or their subsidiaries, or licensees on other markets.[79]

This, they argued, was a retreat from asserting its rights to use compulsory licencing.

At the press conference called by the Minister of Health later the same day, much of the focus of media questions was on whether the Minister would now use the powers given to her by the Act to import generic antiretroviral medicines. This line of questioning betrayed a lack of knowledge of the compromise referred to above. The Minister's response was to pour cold water on the ebullient mood by stating categorically that it was not government policy to use antiretroviral medicines – nor would it be for the foreseeable future. A slightly more conciliatory approach was adopted by Dr Ntsaluba, the Director General.

But despite this there is no doubt that the TAC *amicus* and the international campaign achieved a great deal. A three-year legal battle had dissolved, freeing the government to implement the Act. Internationally, the intense focus on medicines, prices, patents and rights to health greatly broadened the support-base of an incipient movement that seeks to treat health as a human right and to promote the idea that commodities such as medicines, that are essential for health, should be treated differently under patent law to commodities that do not have any intrinsic link to human dignity and well-being. This conviction undoubtedly had an impact on the negotiations around TRIPS which took place at the World Trade Organisation's (WTO) Ministerial Conference in Doha in November 2001.

79 Heads of Argument of the Respondent, 17th April 2001, para 76.1.

The Declaration on TRIPS (which recognises that "Each member has the right to grant compulsory licences") reflects the greater confidence of developing countries to defend rights to health against incursions by multi-national companies based on their interpretation of trade rules.[80]

On another level, it provided proof that the world's most powerful multi-national companies are not invincible and can be brought to account by well researched, well argued mobilisations. This lesson will undoubtedly inspire other social struggles.

At a national level, the TAC's campaign against the PMA deepened and broadened civil societies' understanding of certain aspects of socio-economic rights and its ability to mobilise around these questions. It provided an important example of relationships that can be built between lawyers, doctors and a range of other interested parties. For example, it poses the question as to whether, if a similar campaign were mobilised around other important legal struggles – such as the one that led to a Constitutional Court judgment on rights of access to land and housing in 2000[81] – there wouldn't be greater impetus for turning significant and symbolic legal rulings into bricks, mortar and stone.

Finally, the court case brought a number of tangible and real benefits for people in need of medicines, including people living with HIV. As already mentioned, international pressure on the pharmaceutical companies brought down the price of a basket of antiretrovirals, making these medicines available in the private sector for a third of their cost of six months before. Potentially, this means that South Africa could expand the number of people benefiting from the use of these medicines from roughly 10 000 to ± 150 000. In addition to this, the sections of the Act dealing with generic substitution will bring about great savings to the ordinary consumer of medicines – estimated by some to be in the region of R2 billion per year.[82]

The previously uncontrollable monopoly of the pharmaceutical companies in South Africa has been weakened and they must now operate within a legal framework that exercises some control over prices and has broken the chain of perverse incentives that previously kept medicine prices high.

On June 1st, the government published the regulations that must accompany the Act and it is expected that the Act will be brought into force by the end of 2001.

Of course, the campaign did not achieve everything. Access of very poor people to antiretrovirals remains dependent upon further price reductions and a change in government policy. But even here, the ground

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80 Declaration on the TRIPS Agreement and Public Health, Ministerial Conference, Fourth Session, (WT/MIN(01)/DEC/W/2).

81 *Government of the Republic of South Africa v Irene Grootboom and others* 2000 (1) SA 46 (CC).

82 *The Sunday Times*, April 22 2001, reported "South Africans are set to benefit to the tune of R2.5 billion ($280 million) in a radical overhaul of the medicines industry... Figures released on Friday by IMS South Africa, a pharmaceutical research company, show that South Africa spent R6.9 billion on branded medicines [in 2000] compared to R970 million on generics."

has shifted. In its Replying Affidavit to the PMA's Answering Affidavit to TAC, the Director General of the Health Department, deposing on behalf of the government, states repeatedly under oath that affordability is the sole barrier to use of antiretrovirals. For example, at paragraph 40.1 he states:

> I dispute that cost considerations are not the main or the major obstacles preventing the use of anti-retroviral medicines in the state and public sector.

At paragraph 61.1:

> . . .the non-use of antiretroviral medicine in the public sector is clearly due to its unaffordability.

At paragraph 66:

> It is price that prevents the use of anti-retroviral medicines in the public sector.

These unambiguous admissions have laid the foundations for the next stage of the TAC's mobilisation as well as for further litigation. Access to antiretrovirals – as part of a greatly improved continuum of health care – is vital to preserve and improve the lives of hundreds of thousands of people with HIV. If the TAC and its allies are able to bring prices into the realm of affordability for the public sector, it will be impossible for government to sustain its current catalogue of excuses, largely brought forward to mask the ideological opposition of the Presidency, to the use of these medicines.

A court application for a compulsory licence repeating many of the arguments brought by the TAC in the PMA matter will soon be launched. It will commence from a much stronger base in the light of the role of the *amicus curiae* and its allies in this case.

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Appendix 1

Table 1: Chronology of key dates – The Battle in the Courts

Date (2001)	
15 & 16 January	TAC's National Executive Committee meets in Cape Town.
26 January	TAC's letter to Applicants and Respondents seeking admission as *Amicus Curiae*.
6 February	Reply to TAC from PMA's attorneys.
14 February	Reply to TAC from the government.
16 February	TAC Founding Affidavit and Notice of Motion served on parties and filed with Pretoria High Court.
22 February	Answering affidavit of PMA, Deeb.
1 March	*Amicus*'s Replying Affidavit to PMA.
5 March	Argument begins in the Pretoria High Court.
6th March	Judge Bernard Ngoepe admits TAC as *amicus* and instructs Applicants and Respondents to reply to allegations made in TAC's Founding Affidavit. The case is postponed to 18 April.
28 March	PMA's Answering Affidavit to TAC's Founding Affidavit is filed.
10 April	TAC and the government's Replying Affidavits to the PMA are filed.
17 April	TAC's Heads of Argument are filed with the Court and served on parties.
18 April	The court case resumes and is quickly adjourned at the request of the PMA.
19 April	The PMA withdraws the matter unconditionally.
1 June	The government publishes a *Government Gazette* with draft Regulations for the Act.

Table 2: Chronology of key dates – The Battle for Public Opinion

Date	
15 & 16 January	TAC's National Executive Committee. Press conference calls for national and international day of action on 5 March.
18 February	TAC leads March of 1 000 people to Parliament in Cape Town. TAC produces Glaxo Wellcome 'AIDS profiteer poster'.

continued

Table 2: Chronology of key dates – The Battle for Public Opinion

1 March	TAC, MSF, Oxfam, COSATU International press conference. Poster published in press calling for people to join the demonstration.
4 March	TAC and COSATU night vigil in Church Square, Pretoria.
5 March	Global day of action: demonstrations in 30 cities world-wide; 250 organisations call for case to be withdrawn.
5 March	5 000 people march past the Pretoria High Court to US Embassy led by church and trade union leaders. National and international demonstrations are headline news world-wide.
6 March	COSATU pickets outside Court continue. European Union passes resolution calling for PMA to withdraw.
18 April	Court case resumes. Pickets held outside Court. Court room packed with TAC volunteers, ANC members, trade union leaders. MSF hands over petition with 250 000 names to PMA.
19 April	PMA withdraws matter. Headline news world-wide. TAC, Oxfam and MSF hold international press conference.

Appendix 2

TAC Internal Memo, April 2001

CURRENT OFFERS ON ARVS MADE TO THE SA GOVERNMENT FOR USE IN THE PUBLIC SECTOR.

Notes

This list is based on documentation contained in the PMA Answering Affidavit to TAC: It does not include prices offered by CIPLA

Although the offers are made to the public sector – and further price reductions can still be brought about by compulsory licensing and activist pressure – a successful campaign to *extend these price offers to the private sector*, could very quickly make access to antiretrovirals affordable to many thousands more people, particularly those with a middle income or who are members of medical aid schemes. TAC could fulfill its mission to save lives.

Essentially what they reveal is that a range of combinations of triple therapy (2 NRTIs and one PI) could be immediately available at between R6 000 and R8 000 per year (or R500 to R660 per month). In this price range the 'Right to Care Initiative' calculates that up to 150 000 people could be using ARVs within two years.

Nucleoside Reverse Transcriptase Inhibitors:

Didanosine & (Videx; ddI) and Stavudine (Zerit; d4T): offered together for $1 per day (approx R8/day; R2 ,920 per annum)
Company: BMS

Zidovudine (AZT/ Retrovir) 1.02 pounds / day (approx R10 per day; R3 650 per annum);
Lamivudine (3TC, Epivir) 40 pence per day (approx R4 per day; R1 460 per annum);
Combivir (AZT & 3TC) 1.30 pounds per day (approx R13 per day; R4 745 per annum)
Company: Glaxo Wellcome

Non-Nucleoside Reverse Transcriptase Inhibitors:

Efavirenz (Stocrin) $1.30 per day ($500 per annum) (approx R10 per day; R3 650 per annum);
Company: MSD

Nevirapine (Viramune) – free for MTCT
Company: Boehringer Ingelheim

Protease Inhibitors:

Indanivir (Crixivan) $1.60 per day ($600 per annum) (approx R8 per day; R2 920 per annum);
Company: MSD