

IN THE COMPETITION COMMISSION OF SOUTH AFRICA

In the complaint submitted by:

TREATMENT ACTION CAMPAIGN

Concerning the conduct of:

MSD (PTY) LTD

MERCK & CO., INC. AND RELATED COMPANIES

AFFIDAVIT OF ZACKIE ACHMAT

I, the undersigned

ABDURRAZACK “ZACKIE” ACHMAT

do hereby solemnly affirm:

1. I am the chairperson of the Treatment Action Campaign (“the TAC”), the complainant in this matter. I am also a founding member of the TAC. I reside in Muizenberg, Cape Town.
2. I have been authorised by the TAC to depose to this affidavit on its behalf. In this regard, I refer attention to a resolution of its National Executive Committee (“the NEC”) dated 2 November 2007, attached marked **Annexure TAC1**.
3. The facts contained herein are true and correct and within my knowledge, unless the context indicates otherwise.
4. I can be contacted on 021 788 5058 or zackie@tac.org.za should the Competition Commission (“the Commission”) wish to obtain further information from me.

5. I have read the statement of complaint, and insofar as it pertains to me and/or the TAC, confirm its contents.
6. In this affidavit, I deal with the following three issues:
 - a. First, I describe the TAC and its work;
 - b. Second, I highlight some of the TAC's work to ensure access to a sustainable supply of affordable HIV-related medicines; and
 - c. Third, I set out the TAC's previous interactions with the Commission and the Competition Tribunal ('the Tribunal').

The TAC

7. The TAC is a not-for-profit company incorporated in terms of section 21 of the Companies Act. It has legal capacity to sue and be sued in its own name. Its head office is at 34 Main Road, Muizenberg, Cape Town. A copy of the TAC's Constitution is attached marked **Annexure TAC2**.
8. The TAC campaigns for the rights and health of people living with HIV/AIDS in South Africa. It brings this complaint to further its own aims (as set out in its Constitution); on behalf of the many HIV-positive people who cannot do so in their own name through lack of knowledge and/or lack of access to legal representation; and in the broader public interest.
9. As described in Article 4 of its Constitution, the principal objectives of the TAC are to –
 - a. Campaign for equitable access to affordable treatment for all people with HIV/AIDS;
 - b. Campaign for and support the prevention and elimination of all new HIV infections;
 - c. Promote and sponsor legislation to ensure equal access to social services for and equal treatment of all people with HIV/AIDS;

- d. Challenge by means of litigation, lobbying, advocacy and all forms of legitimate social mobilisation, any barrier or obstacle, including unfair discrimination, that limits access to treatment for HIV/AIDS in the private;
 - e. Educate, promote and develop an understanding and commitment within all communities of developments in HIV/AIDS treatment;
 - f. Campaign for access to affordable and quality health care for all people in South Africa;
 - g. Train and develop a representative and effective leadership of people living with HIV/AIDS on the basis of equality and non-discrimination irrespective of race, gender, sexual orientation, disability, religion, sex, socio-economic status, nationality, marital status or any other ground; and
 - h. Campaign for an effective regional and global network comprising of organisations with similar aims and objectives.
10. At its launch on 10 December 1998, TAC's founding members demonstrated outside St Georges Cathedral in Cape Town. They called on government to develop and implement a comprehensive and affordable treatment plan for all people living with HIV/AIDS.
 11. The TAC's largest programme is the production and dissemination of treatment education, which is known as its Treatment Literacy Programme. This programme has involved training over 200 of our members to become experts on the science of HIV prevention and treatment. Currently over 100 of these trained members, on an almost daily basis, provide treatment literacy services in health facilities and other institutions in six provinces. Tens of thousands of people have been educated about the science of HIV in this way.
 12. TAC runs this programme for a number of reasons, but primarily because it is the organisation's view that the provision of HIV prevention and treatment education increases the number of people with HIV who seek timely assistance from the public health system. Treatment literacy also improves adherence to antiretroviral ("ARV") treatment and other HIV-related medications.

13. As an integral part of its work, the TAC produces numerous education materials, including a magazine called *Equal Treatment*, booklets such as *HIV in Our Lives*, *Antiretrovirals in Our Lives*, and *Pregnancy and HIV*; and numerous posters and pamphlets on various aspects of HIV.
14. As I have mentioned, the TAC has its national office in Cape Town. The TAC has provincial offices in the Western Cape, Gauteng, Eastern Cape, KwaZulu-Natal, Limpopo and Mpumalanga, and it has district offices in Lusikisiki and Queenstown (Eastern Cape), Pietermaritzburg (KwaZulu-Natal), Khayelitsha (Western Cape) and Ekurhuleni (Gauteng).
15. There are more than 200 TAC branches across the country, including in the poorest communities in the Eastern Cape (such as Lusikisiki) and at institutions such as the University of Cape Town. Most of our volunteers and staff live in the communities in which they work. Our database lists approximately 12,000 members.
16. A number of organisations and individuals in South Africa are associated with the TAC. They include the Congress of South African Trade Unions (“COSATU”), the Federation of Unions of South Africa (“FEDUSA”), the Southern African Catholic Bishops Conference (“SACBC”), the South African Council of Churches (“SACC”), Habonim Dror, Positive Muslims, the Children’s Rights Centre, Médecins Sans Frontières (“MSF”), the AIDS Consortium, a range of other organisations of people living with HIV/AIDS, and individuals living with HIV/AIDS.
17. Internationally, the TAC is associated with the Pan African Treatment Access Movement (“PATAM”), which is a coalition of various HIV/AIDS treatment-access organisations and individuals across Africa. It is also associated with the International Treatment Preparedness Coalition (“ITPC”).
18. The TAC interacts regularly with the Joint United Nations Programme on HIV/AIDS (“UNAIDS”), the World Health Organisation (“WHO”) and the Global Fund to Fight AIDS,

TB and Malaria (“GFATM”) regarding strategy and policy in respect of treatment for HIV/AIDS. For example, I was appointed to the WHO’s HIV Strategic and Technical Committee in November 2004. The TAC’s treasurer, Mark Heywood, has served as a member of the UNAIDS Reference Group on HIV and Human Rights – which advises UNAIDS “on all matters relating to HIV and human rights” – since its inception in 2002 and currently acts as its chairperson.

19. The TAC has consistently campaigned for access to affordable and quality treatment for all people with HIV/AIDS in South Africa. In this work, the organisation has challenged both government and the private sector – including pharmaceutical companies – to take appropriate action to make information about treatment more widely available, and to increase the availability and affordability of treatment. In addition, the TAC initiated its own Treatment Project to raise funds to provide treatment for its own members and others in their communities with advanced HIV-disease.
20. The TAC and I have received a number of awards and commendations from prestigious organisations for our work, including (not limited to) the following:
 - a. The first Desmond Tutu Leadership Award (2002);
 - b. Nelson Mandela Health and Human Rights Award (2003);
 - c. Jonathan Mann Award for Global Health and Human Rights (2003); and
 - d. Silver Rose Award for Social Justice (2003).
21. The American Friends Service Committee (better known as the Quakers) nominated the TAC and me for the 2004 Nobel Peace Prize.

TAC work to ensure access to a sustainable supply of affordable HIV-related medicines

22. I discuss here a sample of the TAC’s work in campaigning to ensure access to a sustainable supply of affordable HIV-related medicines.

23. In 2000, the TAC campaigned for the pharmaceutical company Pfizer to reduce the price of its essential antifungal drug fluconazole, which was still under patent protection at that time. When Pfizer refused the TAC's request to charge an affordable price or to grant voluntary licences for the local production and/or importation of significantly cheaper generic fluconazole, the TAC launched a defiance campaign named after Christopher Moraka, a TAC member who had died because he could not access this essential medicine. As a result of this campaign, Pfizer donated – and continues to donate – fluconazole to the public health system in terms of its Diflucan Partnership Programme.
24. In early 2001, the TAC was admitted as *amicus curiae* by the Transvaal High Court in the case of *Pharmaceutical Manufacturers' Association of South Africa and Others v Government of the Republic of South Africa and Others* (case no: 4183/98). In that case, the Pharmaceutical Manufacturers' Association of South Africa and its co-applicants sought to prevent President Mandela from bringing into force the Medicines and Related Substances Control Amendment Act 90 of 1997 ("Act 90 of 1997"), which introduced various medicines access-friendly measures to South African law. In support of its legal intervention and government's defence of the legislation, the TAC organised worldwide demonstrations against the applicants in that case. Within six weeks of the TAC's admission as *amicus curiae*, the applicants dropped their legal action.
25. Also in 2001, the TAC held demonstrations against the pharmaceutical company Bristol-Myers Squibb ("BMS") to compel it to meet its promise to reduce the combined price of two ARV medicines – stavudine ("d4T") and didanosine ("ddl") to \$1 per person per day. Following the TAC activities, this price reduction was indeed implemented. Today, both d4T and ddl are provided as part of ARV treatment in the public sector.
26. In 2004, the TAC was admitted as *amicus curiae* in the Supreme Court of Appeal ("the SCA") and the Constitutional Court, in the challenge by New Clicks, the Pharmaceutical Society of South Africa and others to the medicine pricing regulations issued in terms of the Medicines and Related Substances Act 101 of 1965 (as amended by Act 90 of 1997). In its intervention, the TAC addressed the right to have access to health care

services in section 27 of the Constitution (with a focus on the right of access to medicines, an integral part of the broader health care right), with particular attention being given to the obligations imposed on the state regarding the progressive realization of the right. The SCA and Constitutional Court judgments both incorporated numerous of the rights arguments advanced by the TAC's legal representatives.

27. In early 2005, the TAC and the Southern African HIV Clinicians' Society ("the SAHCS") challenged BMS's pricing of the essential antifungal medicine Amphotericin B ("AmB"), which was being sold in South Africa at an excessive price. AmB is widely used to treat invasive fungal infections, and in particular, is the antifungal agent of choice to treat cryptococcal meningitis, a common cause of death amongst people living with HIV/AIDS in Africa, with a mortality rate of between 25 and 40%. Largely because of its excessive price, AmB was used sparingly in the public sector. Before the TAC and SAHCS were able to lodge a complaint with the Commission, as they had threatened to do, BMS dropped its price by more than 80%.

Previous TAC interaction with the Commission and Tribunal

28. In addition to a July 2000 submission regarding the proposed merger between pharmaceutical companies Glaxo Wellcome and SmithKline Beecham – which subsequently formed the company GlaxoSmithKline ("GSK") – the TAC has submitted two complaints to the Commission: the first in 2002 regarding allegations of excessively priced ARV medicines marketed and sold by GSK and Boehringer Ingelheim ("BI"); and the second in 2004 primarily regarding allegations of price-fixing by members of the National Pathology Group ("the NPG").
29. The latter complaint resulted in significant changes in the way the NPG's members conduct their businesses, as well as a further complaint instituted by the Commissioner into various practices in the pathology sector. The Commission's investigation into the pricing of key ARV medicines sold by GSK and BI revealed that the two companies had indeed abused their dominant positions in the relevant markets. The matter was settled between the parties, thus obviating any need for a Tribunal hearing.

30. The former complaint – which was initially lodged by four TAC members (Hazel Tau, Nontsikelelo Zwedala, Sindiswa Godwana and Isaac Skosana), four health care workers (Sister Susan Roberts, Dr William Mmbara, Dr Steven Andrews and Dr Francois Venter), COSATU, the Chemical, Energy, Paper, Printing, Wood and Allied Workers' Union and the TAC – alleged that GSK and BI were charging excessive prices for their adult and paediatric formulations of zidovudine (“AZT”), lamivudine (“3TC”) and nevirapine (“NVP”). On 16 October 2003, the Commission indicated that the complaint would be referred to the Tribunal for adjudication. Following its year long investigation, it found that there was evidence to support the referral on the basis of prohibited excessive pricing as well as two additional grounds, both of which dealt with the failure of GSK and BI to license generic manufacturers in certain circumstances.
31. The key terms of the settlement agreements reached between TAC and GSK and BI were as follows:
- a. GSK agreed to grant licences to four generic companies (including Aspen Pharmacare (“Aspen”) and Thembalami Pharmaceuticals) to produce and/or import, sell and distribute AZT and 3TC products. Before the agreement, GSK had only granted a single licence to Aspen.
 - b. BI agreed to grant licences to three generic companies (including Aspen) to produce and/or import, sell and distribute NVP products. Before the agreement, BI had only granted a single licence to Aspen.
 - c. The royalty fee to be paid would be no more than 5% of net sales of the ARV medicines in question. Before the agreements, the royalty fees that GSK and BI requested were 30% and 15% respectively.
 - d. The licences would be for both the private and public sectors. Before the agreements, the licences granted to Aspen were limited to the public sector.
 - e. The agreements would also allow licensees to export AZT, 3TC and NVP products produced in South Africa to all 47 sub-Saharan African countries. Before the agreements, exports to sub-Saharan African countries were not permitted.

- f. The licensees would be able to manufacture AZT, 3TC and/or NVP in combination with each other and/or any other medicines for which the licensees had or did not need licences. This was critical because it would allow certain triple-drug fixed dose combinations – such as the d4T/3TC/NVP combination currently manufactured by at least two generic producers – to come to market.
- g. The licences would cover both adult and paediatric formulations of AZT, 3TC and NVP.

32. The effect of the agreements on the prices of these medicines has been dramatic:

- a. When the complaint was lodged in 2002, the private sector price for a 30-day supply of 150mg 3TC was R729.60. The lowest private sector price for a generic equivalent today is R44.40, representing a price reduction of 93.9%.
- b. Significant price reductions have been seen in respect of other 3TC products, as well as in respect of AZT and NVP products:
 - i. 240ml 3TC solution: was R267.90; now R62.88 (76.5% reduction);
 - ii. AZT/3TC combination: was R912.00; now R250.80 (72.5% reduction);
 - iii. 300mg AZT: was R663.48; now R225.00 (66.1% reduction);
 - iv. 200ml AZT solution: was R157.46; now R62.89 (60.1% reduction); and
 - v. 200mg NVP: was R410.40; now R171.00 (58.3% reduction).
- c. Competition in respect of 3TC and NVP has reduced the public sector price for the standard first-line ARV treatment regimen of d4T, 3TC and NVP to about R110 per patient per month. The best price for this regimen offered by the relevant patent holders to developing county governments at the time the complaint was lodged in 2002 was US\$727 per patient per year, or more than US\$60 per patient per month.

**SIGNED AND AFFIRMED BEFORE ME AT _____ ON THIS THE ____
DAY OF NOVEMBER 2007, THE DEPONENT HAVING STATED THAT HE KNOWS AND
UNDERSTANDS THE CONTENTS OF THIS AFFIDAVIT, THAT HE HAS NO OBJECTION
TO MAKING THE SOLEMN AFFIRMATION AND THAT HE CONSIDERS THE SAME AS
BINDING ON HIS CONSCIENCE.**

COMMISSIONER OF OATHS