

IN THE COMPETITION COMMISSION OF SOUTH AFRICA

In the complaint submitted by

HAZEL TAU	First Complainant
NONTSIKELELO PATRICIA ZWEDALA	Second Complainant
SINDISWA GODWANA	Third Complainant
ISAAC MTHUTHUZELI SKOSANA	Fourth Complainant
SR SUSAN ROBERTS	Fifth Complainant
DR WILLIAM NKHANGWENI MMBARA	Sixth Complainant
DR STEVEN MURRAY ANDREWS	Seventh Complainant
DR WILLEM DANIEL FRANCOIS VENTER	Eighth Complainant
CONGRESS OF SOUTH AFRICAN TRADE UNIONS	Ninth Complainant
CHEMICAL, ENERGY, PAPER, PRINTING, WOOD AND ALLIED WORKERS' UNION	Tenth Complainant
TREATMENT ACTION CAMPAIGN	Eleventh Complainant

concerning the conduct of

GLAXOSMITHKLINE SOUTH AFRICA (PTY) LTD

GLAXO GROUP LIMITED AND RELATED COMPANIES

BOEHRINGER INGELHEIM (PTY) LTD

INGELHEIM PHARMACEUTICALS (PTY) LTD

BOEHRINGER INGELHEIM GMBH AND RELATED COMPANIES

**STATEMENT OF COMPLAINT IN TERMS OF SECTION 49B(2)(b) OF THE COMPETITION
ACT 89 OF 1998**

1. The first complainant is **HAZEL TAU**, an adult female residing in Soweto, Gauteng. (Affidavit annexed marked **Annexure HT**)
2. The second complainant is **NONTSIKELELO PATRICIA ZWEDALA**, an adult female residing in Kosovo squatter camp in Phillipi, Cape Town. (Affidavit: **Annexure NPZ**)
3. The third complainant is **SINDISWA GODWANA**, an adult female residing in Section 1 Squatter Camp in Phillipi, Cape Town. (Affidavit: **Annexure SG**)
4. The fourth complainant is **ISAAC MTHUTHUZELI SKOSANA**, an adult male residing in Johannesburg. (Affidavit: **Annexure IMS**)
5. The fifth complainant is **SR SUSAN ROBERTS**, an adult female nurse who submits this complaint in her personal capacity. (Affidavit: **Annexure SR**)
6. The sixth complainant is **DR WILLIAM NKHANGWENI MMBARA**, an adult male practising doctor who submits this complaint in his personal capacity. (Affidavit: **Annexure WNM**)
7. The seventh complainant is **DR STEVEN MURRAY ANDREWS**, an adult male practising doctor who submits this complaint in his personal capacity. (Affidavit: **Annexure SMA**)
8. The eighth complainant is **DR WILLEM DANIEL FRANÇOIS VENTER**, an adult male practising doctor who submits this complaint in his personal capacity. (Affidavit: **Annexure FV**).
9. The ninth complainant is the **CONGRESS OF SOUTH AFRICAN TRADE UNIONS (COSATU)** a body corporate and a federation of trade unions registered under the Labour Relations Act 66 of 1995. (Affidavit: **Annexure ZV**)

10. The tenth complainant is the **CHEMICAL, ENERGY, PAPER, PRINTING, WOOD AND ALLIED WORKERS' UNION (CEPPWAWU)** a trade union registered in terms of the Labour Relations Act and a body corporate. (Affidavit: **Annexure WN**)
11. The eleventh complainant is the **TREATMENT ACTION CAMPAIGN (TAC)**, an association incorporated under section 21 of the Companies Act 61 of 1973 with its head office at 34 Main Road, Muizenberg, Cape Town, Western Cape. (Affidavit: **Annexure PMR**)

THE SUBJECTS OF THE COMPLAINT

12. The first subject of the complaint is **GLAXOSMITHKLINE SOUTH AFRICA (PTY) LTD (GSK)**, a company duly incorporated under the laws of South Africa and with its registered office at 44 Old Pretoria Road, Midrand. GSK is cited because to the best of the complainants' knowledge it has and exercises the exclusive right to market and sell GlaxoSmithKline antiretroviral medicines (ARVs) in South Africa, as the South African representative of the GlaxoSmithKline group of companies. GSK has the exclusive right to market and sell the following ARVs in South Africa:
 - 12.1 Zidovudine (AZT), branded as Retrovir[®];
 - 12.2 Lamivudine, branded as 3TC[®];
 - 12.3 Abacavir (ABC), branded as Ziagen[®];
 - 12.4 Amprenavir, branded as Preclir[®];
 - 12.5 AZT/lamivudine, branded as Combivir[®]; and
 - 12.6 AZT/lamivudine/ABC, branded as Trizivir[®].
13. The complaint is also submitted against **GLAXO GROUP LIMITED (Glaxo Group)** (a researched-based pharmaceutical group of companies with headquarters in the United Kingdom (UK)) as well as related companies in the same group insofar as they participate in the conduct referred to in this complaint. Glaxo Group is housed at Glaxo Wellcome House, Berkely Avenue, Greenford, Middlesex, UB6 0NN, United Kingdom. The complainants have been unable to ascertain which particular companies related to Glaxo Group have the right to sell and market the pharmaceutical products that are the

subject of this complaint to or in South Africa. The complainants request that this information be obtained by the Competition Commission (the Commission) during the course of its investigations. As at October 2001, Glaxo Group was registered in South Africa as the patentee of Patent 97/9726. The title of the invention of this patent is “Pharmaceutical compositions.” This patent covers the active ingredients lamivudine and AZT in the product branded as Combivir®. Its address for service under section 87 of the Patents Act, 57 of 1978 is DM Kisch Inc, 66 Wierda Road, East Wierda Valley. GlaxoSmithKline Services Unlimited is a company registered under the laws of England and Wales with registration no 1047315 and with its registered office at 980 Great West Road, Brentford, Middlesex, TW8 9GS. GlaxoSmithKline has used the GlaxoSmithKline Services Unlimited letterhead in correspondence with the Treatment Action Campaign (TAC) regarding voluntary licenses and increasing access to ARVs. For convenience, the name “GlaxoSmithKline” is used in the body of the Statement of Complaint to refer to the group internationally and “GSK” to refer to the relevant South African company.

14. A further subject of the complaint is **BOEHRINGER INGELHEIM (PTY) LTD** (Boehringer) a company registered under the laws of South Africa with its registered offices at 404 Main Avenue, Randburg. To the best of the complainants’ knowledge, Boehringer has the exclusive right to market and sell the ARV nevirapine—branded as Viramune®—in South Africa. Boehringer is a South African operation of the CH Boehringer group which is a research-based group of pharmaceutical companies headquartered in Ingelheim, Germany. The group is also represented in South Africa by **INGELHEIM PHARMACEUTICALS (PTY) LTD** (Ingelheim) which has its registered office at the same address as Boehringer, namely 404 Main Avenue, Randburg. Ingelheim appears on the package insert for Viramune® tablets as the applicant for registration of those products at the Medicines Control Council (MCC). The complainants have been unable to ascertain whether Ingelheim is acting as an agent for the patentees or whether it has also been granted a licence. However Boehringer has utilised its letterhead for the purposes of correspondence with the TAC in relation to voluntary licenses as representative of the company based in Germany. Should it transpire during the course of investigations that only Ingelheim or only Boehringer has the right to market and sell nevirapine (Viramune®) within South Africa then the

complainants confine their complaint in this regard to the relevant company. For present purposes and to ensure that the Commission is able properly to investigate the complaint, both companies are cited.

15. A further subject of the complaint is **BOEHRINGER-INGELHEIM INTERNATIONAL GMBH** and/or those companies that are related to it and that have the right to market and sell nevirapine (Viramune[®]) to any entity in South Africa (including Boehringer and/or Ingelheim). The companies are members of a multinational group of companies generally known as “the Boehringer Ingelheim group of companies”. An organogram of the corporate structure of the group which forms part of the Consolidated Financial Statements 2001 is annexed marked **Annexure A**. As at October 2001 **BOEHRINGER INGELHEIM PHARMACEUTICALS INC** of 90 East Ridge, Ridgefield, Connecticut, 06877, USA and **DR KARL THOMAE GMBH** OR d-7950, Biberach an der Riss, Germany, whose address for service under section 87 of the Patents Act, 57 of 1978 is DM Kisch Inc, 66 Wierda Road, East Wierda Valley, Sandton, 2146 are registered in South Africa as the patentees of Patent 90/9246. This patent covers the active ingredient nevirapine in the product branded as Viramune[®]. The name “Boehringer-Ingelheim” is used in the body of the Statement of Complaint to refer to the group internationally.
16. For convenience the subjects of the complaint are referred to below collectively as “the respondents”.

NATURE OF THE COMPLAINT

17. The complainants allege that the companies that are the subject of this complaint have engaged in excessive pricing of ARVs to the detriment of consumers, as prohibited by section 8(a) of the Competition Act, 89 of 1998 (the Act). The excessive pricing of ARVs is directly responsible for premature, predictable and avoidable deaths of people living with HIV/AIDS, including both children and adults. The ARVs in respect of which excessive pricing is alleged are as follows:

17.1 AZT (branded as Retrovir[®]);

- 17.2 Lamivudine (branded as 3TC®);
- 17.3 AZT/lamivudine (branded as Combivir®); and
- 17.4 Nevirapine (branded as Viramune®)

18. The complainants also allege that in so far as these ARVs are concerned, the respondents are dominant firms as contemplated by section 7 of the Act. In the result, the prohibition in the Act against excessive pricing to the detriment of consumers is applicable. The relevant markets in which dominance is alleged are detailed below.
19. The complainants further allege that the respondents satisfy the threshold requirements in section 6 of the Act. In the 2002 financial year, the gross revenue of each of the respondents from income in, into or from South Africa, arising from the transactions set out in item 3(1) of the Schedule to the Determination of Threshold in terms of Section 6(1) of the Act, has exceeded the threshold at ZAR 5 million as contained in Government Notice 562 in *Government Gazette* 22128 dated 9 March 2001.

STATE OF THE HIV/AIDS EPIDEMIC IN SOUTH AFRICA

20. According to the 12th *National HIV and Syphilis seroprevalence survey in SA (2001)*, the National Department of Health (the Department) estimates that there are approximately 4.74 million South Africans living with HIV/AIDS. A copy of the survey is attached hereto marked **Annexure B**. A report released by the Medical Research Council (MRC) in 2001 (“the MRC report”) indicates that AIDS is now the leading cause of mortality in South Africa, with approximately 200 000 people being estimated to have died of an AIDS-related illness in 2001 alone. A copy of the MRC report entitled *The Impact of HIV/AIDS on Adult Mortality in SA* is attached hereto marked **Annexure C**.
21. The MRC report estimates that about 40% of adult deaths aged 15-49 in 2000 were due to HIV/AIDS, and that about 20% of all adult deaths in that year were AIDS-related. Most of these people died without having access to medicines that could have prolonged and improved the quality of their lives. Without appropriate treatment to prevent and/or delay the onset of AIDS in people living with HIV, the MRC forecasts that “the number of AIDS deaths can be expected to grow, within the next 10 years to more

than double the number of deaths due to all other causes, resulting in 5-7 million cumulative AIDS deaths in South Africa by 2010". (**Annexure C, p6**)

22. Because of its nature and extent, the HIV/AIDS epidemic has the potential to weaken existing health infrastructure and health service delivery substantially. The Department of Health itself recognises that HIV/AIDS represents the "greatest threat to public health in our country". In this regard see the (unreported) case of *Minister of Health and Others v Treatment Action Campaign and Others*, CCT 8/02 (5 July 2002) at paragraphs 1 and 93. A copy of the judgment is attached hereto marked **Annexure D**.

23. The Constitutional Court recognises that it "is essential that there be a concerted national effort to combat the HIV/AIDS pandemic", and that it is "important that all sectors of the community ... should co-operate in the steps taken to achieve this goal." See in this regard *Minister of Health and Others v Treatment Action Campaign and Others, supra* at paragraphs 125-126. Implicit in the Court's finding is that all stakeholders, including government, labour, civil society and business, have a role to play in dealing with the HIV/AIDS epidemic. It is in this context that the complaints about excessive pricing are made.

TREATING HIV/AIDS—HIGHLY ACTIVE ANTIRETROVIRAL THERAPY (HAART)

24. ARVs are medicines that specifically target HIV infection itself rather than the opportunistic infections that are associated with HIV/AIDS. These drugs are combined in various different treatment regimens that collectively are known as highly active antiretroviral therapy (HAART). HAART has revolutionised the management of HIV infection, resulting in a radical reduction in mortality and morbidity figures amongst groups with access to the new treatment therapies. Additional health benefits include the reduction and/or elimination of opportunistic infections, the restoration of immune function and a reduction in infectiousness. A more detailed medical and scientific explanation of HAART is contained in an affidavit by Professor Robin Wood annexed marked **Expert Annexure RW**.

25. The ARVs available in South Africa can be divided into three therapeutic classes:

- 25.1 Nucleoside analogue reverse transcriptase inhibitors (NRTIs):
AZT, lamivudine, ABC, stavudine (d4T), didanosine (ddl) and zalcitabine (ddC);
- 25.2 Non-nucleoside reverse transcriptase inhibitors (NNRTIs):
nevirapine and efavirenz;
- 25.3 Protease inhibitors (PIs):
nelfinavir, indinavir, ritonavir, saquinavir (hard gel capsule), saquinavir (soft gel capsule), amprenavir and lopinavir.

26. Of these ARVs, nine are available in paediatric formulations:

- 26.1 NRTIs: AZT, lamivudine, ddl, d4T and ABC;
- 26.2 NNRTIs: nevirapine; and
- 26.3 PIs: nelfinavir, ritonavir and amprenavir.

27. Some of these ARVs are also available in various fixed-dose combination forms. The only combinations currently available in South Africa are AZT/lamivudine and lopinavir/ritonavir. GlaxoSmithKline's Trizivir[®] (AZT/lamivudine/ABC) is not yet commercially available in South Africa.

28. ARVs target either a particular step in the life cycle of HIV or its interaction with host cells. The ARVs in general use in South Africa inhibit one of two key viral enzymes required by HIV for viral replication, targeting either reverse transcriptase (essential for the completion of the early stages of HIV replication) or protease (required for the assembly and maturation of new HIV).

29. Since 1996, HAART has been the standard of care in Europe, North America and Brazil. Scientific consensus confirms that at least three drugs should be used together in the treatment of HIV to ensure maximum clinical efficacy, reduce side effects and limit the emergence of resistant strains of the virus. The simultaneous use of three or more drugs, including drugs from different therapeutic classes, is essential for both individual clinical outcomes and public health protection. In his affidavit, Professor Wood explains the way in which ARVs are combined to create regimens that work and shows that it is

necessary to have access to a combination of drug choices both within and between drug classes. The ability to devise different drug regimens allows practitioners to take into account problems such as proven antagonism between specific drugs, potency and side effect profile, potential for maintenance of future treatment options, pregnancy, potential for primary acquisition of resistant viral strains, the incidence of tuberculosis (TB) and hepatitis B and/or C, amongst other factors. All these factors have an influence on what drug regimen is selected.

30. The World Health Organisation (WHO) includes ARVs on the Core List of its Model List of Essential Drugs (12th edition, April 2002). A copy of the Model List is attached hereto marked **Annexure E**. In deciding that all recommended drugs should be included in the Model List, the WHO Expert Committee on the Selection and Use of Essential Medicines (the Committee) states as follows:

“While accepting that there were many circumstances in medicine where one essential drug may substitute easily for other members of a class, thus allowing the placement of a single agent on the Model List (with appropriate advice about substitution), this was not possible with HIV treatment. Effective therapy requires commencement of three drugs simultaneously, and alternative regimens are necessary to meet specific requirements at start-up, to substitute for first-line regimens in the case of toxicity, or to replace failing regimens. The committee considered various approaches to the listing of these agents but agreed finally that if they were to be listed, all drugs recommended should be included in the Model List.”

A copy of the Committee’s notes on the inclusion of new items on the Model List is attached hereto marked **Annexure F**.

31. The ARVs included on the WHO Core List are AZT, lamivudine, ABC, d4T, ddI, nevirapine, efavirenz, indinavir, lopinavir/ritonavir, nelfinavir, ritonavir and saquinavir. The Model List makes it clear that “[s]election of two or three protease inhibitors ... will need to be determined by each country after consideration of local treatment guidelines and experience, as well as the comparative costs of available products.” In relation to NRTIs and NNRTIs, however, no such considerations apply. See **Annexure E**.

32. The significance, simply put, is that the availability of a number of ARVs in a particular therapeutic class does not necessarily mean that people with HIV/AIDS have a choice of products. The science of HIV treatment shows that ARVs are generally not interchangeable, with numerous factors combining to limit or completely exclude treatment combinations and options. See paragraphs 17 to 32 of the affidavit of Professor Robin Wood annexed as **Expert Annexure RW**.

DRUG PRICES: A BARRIER TO ACCESS

33. Tables 1, 2 and 3 below provide pricing information on each product in respect of which an excessive pricing complaint is brought. Table 1 deals with Adult Formulations. Table 2 deals with Paediatric Formulations. The prices referred to in these tables have been investigated and compiled by a researcher at the AIDS Law Project, Jonathan Michael Berger. An affidavit explaining the methods adopted by Jonathan Berger is annexed as **Annexure JMB** and is relevant to Tables 1, 2 and 3. In each instance the US dollar (US\$) price converted to South African rands (ZAR) was done using an exchange rate of US\$1 = ZAR 10,50.
34. These tables are based on prices obtained from GSK and Boehringer themselves, as well as information obtained from a Médecins Sans Frontières (MSF) study entitled “Untangling the Web of Price Reductions: a Pricing Guide for the Purchase of ARVs for Developing Countries” (June 2002, 2nd edition) and a recent press statement issued by GlaxoSmithKline on 5 September 2002. Copies of the study and the press statement are annexed as **Annexure G** and **Annexure H** respectively.

Table 1: ADULT FORMULATIONS PER TABLET/CAPSULE

35. In Table 1, four prices are given for each ARV. In every instance the price is the price per tablet/capsule. This unit has been selected to standardise comparisons and in particular with generic equivalents. All the adult formulations of the drugs that are the subject of this complaint are packaged in packs of 60 tablets/capsules.
36. The first price is the latest available price (in ZAR and exclusive of VAT) charged by the respondents through their local companies (GSK and Boehringer and/or Ingelheim) to

the private sector in South Africa.

37. The second price is the latest available international best price offer (in US\$) for developing countries made by GlaxoSmithKline and Boehringer-Ingelheim internationally. In the case of nevirapine there is no significant difference between the so-called international “best price offer” and the price available to the private sector generally. In the case of the other ARVs that are the subject of this complaint, namely those manufactured by GlaxoSmithKline, the so-called best price offer is significantly lower but is not generally available to the private sector. In this regard see the text at footnote 1 on page 3 of **Annexure H** and footnote 1 at page 4 where the current GlaxoSmithKline policy on who is an eligible customer in this regard is explained.
38. The third price given is the best price offer (US\$) by generic pharmaceutical manufacturers of equivalent products that have been pre-qualified by the WHO. WHO pre-qualification means that the product has been found to be acceptable, in principle, for procurement by United Nations agencies. In this regard see “Access to HIV/AIDS Drugs and Diagnostics of Acceptable Quality”, WHO (11 September 2002, 2nd edition) annexed as **Annexure I**.
39. The fourth price is the best price offer in US\$ by generic pharmaceutical manufacturers producing a generic equivalent of the ARVs concerned. Because these ARVs have not yet been registered by the Medicines Control Council (MCC) of South Africa or have not yet been pre-qualified by the WHO, further reliance has not been placed on this price for purposes of the present complaint.

Table 2: PAEDIATRIC FORMULATIONS PER 100 ML

40. In respect of each product in Table 2, two prices are given. Each price refers to the cost per 100ml of the particular ARV paediatric formulation concerned. This unit has been selected to permit standardised comparison and in particular with generic equivalents.
41. The first price is the latest available price (in ZAR and exclusive of VAT) charged by the respondents through their local companies (GSK and Boehringer and/or Ingelheim) to

the private sector in South Africa.

42. The second price given is the best price offer (in US\$) by generic pharmaceutical manufacturers of products that have been pre-qualified by the WHO.
43. It will be noted that no reference is made in Table 2 to the paediatric formulation of Viramune®. The reason for this is that the complainants had no access to a best price offer of an equivalent product that has been pre-qualified by the WHO. It is pointed out also that there is no Combivir® paediatric formulation.

Table 3: ANNUAL COSTS PER ADULT OR CHILD

44. The prices given in Table 3 are the annual costs per adult or child of using a particular ARV as part of HAART, calculated according to the recommended daily doses contained in a WHO document entitled “Scaling-up Antiretroviral Therapy in Resource Limited Settings: Guidelines for a Public Health Approach” (22 April 2002) annexed as **Annexure J**. The prices given in Table 3 in respect of paediatric formulations are based on the treatment of an average three-year-old girl child.

Table 1: ADULT FORMULATIONS PER TABLET / CAPSULE

Product	Price sold to private sector	International Best Price Offer—branded product	WHO pre-qualified generic	International Best Price Offer—generic
AZT (300mg)	ZAR 9,70 (US\$ 0,92)	(ZAR 6,30) US\$ 0,60	(ZAR 2,59) US\$ 0,25	(ZAR 2,01) US\$ 0,19
Lamivudine (150mg)	ZAR 10,67 (US\$ 1,02)	(ZAR 3,36) US\$ 0,32	(ZAR 1,46) US\$ 0,14	(ZAR 0,95) US\$ 0,09
AZT/lamivudine (300mg/150mg)	ZAR 13,33 (US\$ 1,27)	(ZAR 8,93) US\$ 0,85	(ZAR 3,81) US\$ 0,36	(ZAR 2,93) US\$ 0,28
Nevirapine (200mg)	ZAR 6,00 (US\$ 0,57)	(ZAR 6,30) US\$ 0,60	(ZAR 2,39) US\$ 0,23	(ZAR 1,61) US\$ 0,15

Table 2: PAEDIATRIC FORMULATIONS PER 100 ML

Product	Price sold to private sector	WHO pre-qualified generic
AZT (50mg/5ml solution)	ZAR 69,06 (US\$ 6,58)	(ZAR 21,00) US\$ 2,00
Lamivudine (10mg/ml solution)	ZAR 97,92 (US\$ 9,33)	(ZAR 27,30) US\$ 2,60

Table 3: ANNUAL COSTS PER ADULT OR CHILD

Product	Price sold to private Sector	International Best Price Offer—branded product	WHO pre-qualified generic	International Best Price Offer—generic
AZT (300mg)	ZAR 7 082,46 (US\$ 674,52)	(ZAR 4 599,00) US\$ 438,00	(ZAR 1 890,00) US\$ 180,00	(ZAR 1 470,00) US\$ 140,00
Lamivudine (150mg)	ZAR 7 786,67 (US\$ 741,59)	(ZAR 2 457,00) US\$ 234,00	(ZAR 1 050,00) US\$ 100,00	(ZAR 693,00) US\$ 66,00
AZT/lamivudine (300mg/150mg)	ZAR 9 733,33 (US\$ 926,98)	(ZAR 6 515,25) US\$ 620,50	(ZAR 2 782,50) US\$ 265,00	(ZAR 2 142,00) US\$ 204,00
Nevirapine (200mg)	ZAR 4 380,00 (US\$ 417,14)	(ZAR 4 599,00) US\$ 438,00	(ZAR 1 743,00) US\$ 166,00	(ZAR 1 176,00) US\$ 112,00
AZT (50mg/5ml solution)	ZAR 5 545,52 (US\$ 528,14)	–	(ZAR 1 686,30) US\$ 160,60	–
Lamivudine (10mg/ml solution)	ZAR 4 288,90 (US\$ 408,47)	–	(ZAR 1 195,74) US\$ 113,88	–

45. These tables indicate dramatic differences in prices between what is charged to the private sector generally in South Africa and what is available outside of South Africa in terms of generic alternatives. Generic ARVs are not sold in South Africa because of the protection of patent law. The question that arises, and which is the subject of this complaint, is whether the prices charged by the respondents are excessive to the detriment of consumers within the meaning of section 8(a) of the Act.
46. The complainants submit that the existence of patent protection is not a justification for charging of a price which in all the circumstances is excessive and to the detriment of consumers. Patent protection does not entitle a firm to charge a price which bears no reasonable relation to the economic value of the good concerned. Compare *Parke, Davis and Company v Probel and Others* (Case 24/67) [1968] 30 CMLR 47 at para 5 and Decision 2 (page 60) and *Volvo AB v Erik Veng (UK) Limited* (Case 238/87) [1989] 4 CMLR 122 at para 9.
47. HAART substantially reduces the incidence of opportunistic infections, resulting in substantial reductions in morbidity and mortality rates. In this regard see the affidavits of Professor Robin Wood and Dr Mark Cotton annexed as **Expert Annexure RW** and **Expert Annexure MC** respectively.
48. With access to HAART, people with HIV/AIDS are able to lead longer and healthier lives. Access to treatment directly results in an improved quality of life and the restoration of dignity, allowing people with HIV/AIDS who were previously ill to resume ordinary everyday activities, such as work. In this regard see the affidavits of the following complainants: Sr Susan Roberts (**Annexure SR**), Dr Willem Daniel Francois Venter (**Annexure FV**), Dr William Nkhangweni Mmbara (**Annexure WNM**), Dr Steven Murray Andrews (**Annexure SMA**), COSATU (**Annexure ZV**), CEPWAWU (**Annexure WN**) TAC (**Annexure PMR**), Nontsikelelo Patricia Zwedala (**Annexure NPZ**) and Sindiswa Godwana (**Annexure SG**).
49. The high prices for ARVs charged by the respondents in South Africa are to the

detriment of consumers because these prices limit access to potentially life-saving and life-enhancing treatment. Access to treatment is limited in a variety of ways.

49.1 One of the reasons that has been given for the government's failure to adopt a comprehensive public sector treatment plan, which includes but is not limited to the provision of ARVs, is that "these drugs are too costly for universal access." In this regard see the Cabinet Statement on HIV/AIDS of 17 April 2002, marked **Annexure K**, and the Summary of Government's position following Cabinet's discussion, released by government at the same time and annexed as **Annexure L**. To the extent that the public sector makes provision for treatment of persons living with HIV/AIDS, the treatment options that are at present available are limited without access to ARV treatment. See for example the affidavit of Sr Susan Roberts, **Annexure SR**.

49.2 High prices of ARVs limit access to treatment in the private sector.

49.2.1 For those people who pay for their own treatment, the high drug prices that are charged often result in no treatment, substandard treatment or limited appropriate treatment options in the event of treatment failure. In this regard see the affidavits of the following complainants from the medical profession: Sr Susan Roberts (**Annexure SR**), Dr William Nkhangweni Mmbara (**Annexure WNM**), Dr Steven Murray Andrews (**Annexure SMA**) and Dr Willem Daniel Francois Venter (**Annexure FV**). See too the impact on the lives of lack of access to treatment on the following individual complainants: Nontsikelelo Patricia Zwedala (**Annexure NPZ**), Isaac Mthuthuzeli Skosana (**Annexure IMS**) and Hazel Tau (**Annexure HT**).

- 49.2.2 For low-paid employees high drug prices ordinarily result in no access to HAART. In those cases where the cost of treatment is being carried by the employer, if a person living with HIV/AIDS loses his or her job or cannot continue working because of illness, access to treatment becomes unaffordable. In these respects see particularly the affidavits of Sr Susan Roberts (**Annexure SR**), Dr Willem Daniel Francois Venter (**Annexure FV**) and the affidavits on behalf of COSATU (**Annexure ZW**) and CEPWAWU (**Annexure WN**).
- 49.2.3 Reductions in prices will enable more medical scheme beneficiaries to enjoy the benefits of HAART by providing greater and wider access to these benefits. In this regard see the affidavit of Dr Leon Derek Regensburg annexed as **Annexure LDR** and Alexander Marius van den Heever, annexed marked **Annexure AMVH**. Where medication cover is capped, reductions in prices will alleviate the problem of patients running out of funded treatment before the end of a year. See the affidavit of Sr Susan Roberts (**Annexure SR**).
- 49.2.4 Lower ARV prices would allow for the cost of chronic medical scheme benefits to be reduced. In turn, this would allow for increased access to treatment, as well as alleviating the burden on the public sector. It would also mean that there is greater access to comprehensive treatment in the insured sector. In this regard see the affidavit of Alexander Marius van den Heever (**Annexure AMVH**).
- 49.3 For people living with HIV/AIDS who are receiving treatment through clinical trials or not-for-profit treatment programmes, access to treatment beyond the life of the particular trial or programme will be limited by high prices of ARVs. In this regard see the affidavits of Dr Steven Murray

Andrews (**Annexure SMA**) and Dr Willem Daniel Francois Venter (**Annexure FV**). See too the affidavit of Nontsikelelo Patricia Zwedala (**Annexure NPZ**) and Sindiswa Godwana (**Annexure SG**).

- 49.4 Similarly high prices mean that many employees receiving HAART through workplace treatment programmes may not be able to access it beyond the term of their employment. In this regard see the affidavits of COSATU and CEPPWAWU annexed marked **Annexures ZV** and **WN** respectively. See also a press statement issued by Anglo American on 6 August 2002 annexed as **Annexure M** and obtainable at www.angloamerican.co.uk.
- 49.5 High prices can result in interrupted treatment (for reasons already dealt with above) which has an impact on appropriate and effective disease management. In this regard see the affidavits of Dr Willem Daniel Francois Venter (**Annexure FV**), Sr Susan Roberts (**Annexure SR**) and Dr Steven Murray Andrews (**Annexure SMA**).
- 49.6 High prices have the impacts described above both in the adult and paediatric populations. For children, the detriment might be considered to be particularly grave in the sense that they require access to HAART much sooner after being infected with HIV. In this regard see the affidavit of Dr Mark Frederic Cotton (**Expert Annexure MFC**).
- 49.7 The lack of proper access to treatment results in a demoralised medical profession who battle to provide professional medical services effectively and in a manner that they find morally and ethically conscionable. In this regard see the affidavits of Sr Susan Roberts (**Annexure SR**), Dr Willem Daniel Francois Venter (**Annexure FV**), Dr William Nkhangweni Mmbara (**Annexure WNM**) Dr Steven Murray Andrews (**Annexure SMA**) and Dr Mark Frederic Cotton (**Expert Annexure MFC**).

50. Because high prices result in lack of access to treatment, the high prices of ARVs result in many avoidable opportunistic infections, preventable deaths and the resultant social and financial implications accompanying high levels of morbidity and mortality. Having established this, there can be no doubt that the high prices that are currently being charged in the private sector for ARVs are to the detriment of consumers.
51. The detriment that is caused is particularly grave by virtue of its direct bearing on the ability of consumers fully to enjoy their constitutionally protected rights and in particular the rights to life, dignity and equality, and access to health care services. The high prices also have the effect that the best interests of children cannot properly be served.
52. The complaint will now proceed to demonstrate that the prices charged by the respondents constitute prohibited excessive prices, as contemplated by section 8(a) of the Act. Before doing so, the complaint will set out why the respondents are dominant firms within the meaning of section 7 of the Act.

ESTABLISHING DOMINANCE: SECTION 7 OF THE ACT

53. It is clear that the relevant geographical market for each ARV that is the subject of this complaint is the national South African market. This follows from the fact that the registration of and the authorisation to use and sell medicines in South Africa, rests exclusively with the South African Medicines Control Council (MCC). Other factors supporting such a finding include the national regulation of the medical scheme industry which is currently responsible for financing the bulk of ARV sales in the country and the regulation of patent protection that also takes place at the national level.
54. As a result of the respondents' reliance on patent protection, none of the ARVs that are the subject of this complaint can at present be sold in the South African market in the form of generics. In other words, the respondents' branded ARVs are not substitutable by equivalent products in South Africa. For the purposes of establishing whether the respondents are dominant in a relevant market the remaining question is whether other

ARVs that are available in South Africa can be substituted for the particular ARVs which are the subject of this complaint. In other words, for example, can a patient whose proper and effective treatment requires the use of AZT be satisfactorily treated by the substitution of another ARV available in South Africa.

55. In general, ARVs cannot be considered as substitutable for each other. In order to access HAART, a person living with HIV/AIDS must at a minimum be able to have access to all of the ARVs that are the subject of this complaint. This is because HAART requires the commencement of at least three ARVs simultaneously, with alternative regimens being necessary to meet specific requirements at initiation of treatment and to substitute for regimens in the case of unmanageable side effects or treatment failure. This is explained in more detail in an affidavit by Professor Robin Wood (**Expert Affidavit RW**). See too **Annexures E and F** (dealing with the WHO Model List and the WHO Expert Committee's notes on the inclusion of new items on the Model List). See further the Southern African HIV Clinicians Society Guidelines for HIV Management in Adults, annexed marked **Annexure N**.
56. In the result, each ARV constitutes its own market both in respect of manufacturers and marketers. Coupled with patent protection, the relevant international respondent companies (as manufacturers and suppliers to South Africa) and the relevant South African respondent companies (as marketers within South Africa) are dominant in respect of the South African market for each particular ARV that is the subject of this complaint. In this case, therefore, dominance exists regardless of each firm's share of the market for a particular therapeutic class of ARVs.
57. In the alternative, it is also possible to show that the respondents are dominant firms with respect to each therapeutic class. Our analysis proceeds on the logical assumption that there is no basis for suggesting that, in relation to South Africa, the market share of the manufacturing and supplying respondents is significantly different from that of the market share of the marketing respondents.

57.1 Available information for the 2002 financial year indicates that the South

African market for NRTI sales is worth ZAR71 966 000. GSK is responsible for ZAR60 225 000 worth of sales, or 83.7% of the NRTI market, substantially in excess of the 45% threshold above which the abuse of dominance provisions are automatically triggered. In terms of units sold, of a total market of 18 420 units, GSK sold 9 060; or 49%.

- 57.2 Available information for the 2002 financial year indicates that the South African market for NNRTI sales is worth R17 288 000. Boehringer and/or Ingelheim is responsible for R 8 358 000 worth of sales, or 48.3% of the NNRTI market, also in excess of the 45% threshold above which the abuse of dominance provisions are automatically triggered. In terms of units sold, of a total market of 5 260 units, Boehringer and/or Ingelheim sold 2 500 units, or 47.5%.

DETERMINING EXCESSIVE PRICING

58. Section 8(a) of the Act prohibits a dominant firm from charging “an excessive price to the detriment of consumers”. An “excessive price” is defined in section 1 as “a price for a good or service which—
- “(aa) bears no reasonable relation to the economic value of that good or service; and
 - (bb) is higher than the value referred to in subparagraph (aa)”.
59. To repeat a point made above, the existence of patent protection does not justify charging a price that bears no reasonable relation to the economic value of the particular drug concerned.
60. It is submitted that factors which are relevant in determining whether the relation between a price charged for a good and the economic value of that good is reasonable within the meaning of the Act include the following:
- 60.1 *What the price of the good would be in a competitive market (i.e. in the absence of patent protection) including a normal rate of profit in that context.*

- 60.2 *A reasonable allowance for the recovery of research and development costs, relevant to the production of the good concerned, which other producers and sellers of the equivalent good in a competitive market would not have incurred.*
- 60.3 *Some allowance for additional profit as an incentive for innovation and any unusual entrepreneurial risk.*
- 60.4 *The nature and extent of the detriment to consumers that results from the high price.* Thus, the fact that high prices cause avoidable loss of life and unnecessary suffering must be taken into account. The fact that this affects so many people must also be taken into account as must the fact that HIV/AIDS is the leading cause of mortality in South Africa and is regarded as the greatest health threat confronting South Africa at present.
- 60.5 *The adverse impact of the high prices on constitutionally protected and internationally recognised rights.* The health consequences of lack of access to treatment deprive people of the enjoyment of their constitutionally protected rights to life, dignity and access to health care services. It also deprives children of their right to have their best interests treated as paramount. The right to dignity is foundational to our constitutional order and with the right to life is regarded as one of the most important rights. Access to health care services allows people to live dignified lives. These rights are firmly entrenched in the Constitution and are also recognised at international law.
61. The complainants do not begrudge research-based companies a reasonable opportunity to recover their true R&D costs. The complainants also accept that research-based companies' *incentive* to innovate can lawfully be reflected in a higher rate of profit and thus a higher price than would be charged for generic equivalents. However, this must be reasonable when viewed in the context of the particular market concerned, and the importance of the particular market to the generation of profits to the industry generally. In the recently released HIV/AIDS and Human Rights International Guidelines 2002 issued by the Joint United Nations Programme on HIV/AIDS and the Office of the United

Nations High Commissioner for Human Rights (annexed as **Annexure O**), it is emphasised that the public and the private sector should support research and development of health needs in developing countries and to help make the prevention, treatment, care and support of HIV/AIDS widely affordable (paragraphs o and p, p.16). Particular mention is made of the need for accessibility of ARVs in Guideline 6 (p.13). While the private sector must be encouraged to innovate, it can never be suggested that it is reasonable to place a premium on incentive to innovate to the point where general access to treatment is denied.

62. With these considerations in mind, the statement of complaint proceeds to show that the prices charged by the respondents are grossly disproportionate to the economic value of the goods even when taking into account the cost of production, research and development (R&D) costs and an appropriate rate of profit. We will show that the respondents' profits exceed any legitimate norm and that in the circumstances the prices charged do not bear any reasonable relation to the economic value of the goods and are thus excessive within the meaning of section 8(a) of the Act.
63. The approach of the Commission to the matter of excessive pricing is dealt with in "Excessive pricing, fairness and economic value", appearing in a publication of the Commission entitled Competition News (September 2001). A copy of the article is annexed as **Annexure P**. In this article, the Commission stated that—
- "[i]t may be necessary to take a pragmatic approach to the analysis of excessive pricing. Such an approach may be as follows: in order to establish economic value, a cost-based approach should be followed, taking the manufacturing costs of the particular product into account, with an industry norm profit margin added. It may also be necessary to add premiums for special circumstance, i.e. risk, cost of innovation or intellectual property, etc." (at page 7)
64. In the case of the pharmaceutical industry, the normal rate of profit obtained by generic manufacturers is unlikely to correspond to that obtained by companies heavily protected by patents. It is noteworthy that the average return on revenues in the pharmaceutical industry, namely 16.2%, is substantially higher than the average return of 7.92% of the top ten industries. In this regard, see **Annexure Q**, which is an extract from "The 2002

Global 500: Top Performing Companies and Industries (Industries: Return on Revenues)” published in Fortune Magazine, 22 July 2002, and obtained from www.fortune.com/lists/G500/g500_topperf_ind_returnrev.html. See further, below. In our submission it will be necessary for the Commission, by using its powers of investigation, to obtain detailed information from the respondents and others in order to ascertain both the true relevant R&D costs and the actual rates of return which they are enjoying in respect of the ARVs which are the subject of the complaint. The pharmaceutical industry is notorious in its refusal to make publicly available this information. However, the respondents cannot withhold the Commission from an investigation carried out in terms of the Act.

65. Even in the absence of such an investigation, there is at least powerful prima facie evidence that grossly excessive prices are being charged by the respondents for the ARVs in question, contrary to the provisions of the Act. This can be demonstrated by making assumptions most favourable to the respondents in respect of R&D costs and a “normal” rate of return.

66. In Table 4 (adult formulations) and Table 5 (paediatric formulations) below, an estimate is made up of “economic value” of the ARVs in question which takes the prices charged by manufacturers of pre-qualified generics, treats these prices as if they were manufacturing costs, and adds to them also a reasonable allowance for R&D, licensing costs where applicable, and the average rate of return on revenue in the pharmaceutical industry. The resulting figures almost certainly result in an inflated estimate of the “economic value” (including profit) of the ARVs concerned. In other words, the estimate is generous to the respondents. The actual prices charged by the respondents to the private sector in South Africa are then compared with the estimated “economic value” in respect of each ARV. In each case, actual price is grossly in excess of the estimated “economic value”.

Table 4: COMPARISON BETWEEN PRICE CHARGED AND ECONOMIC VALUE: ADULT FORMULATIONS

Product	Price charged to private sector	WHO pre-qualified generic	Estimated economic value	Ratio: private sector to economic value
AZT (300mg)	ZAR 9,70 (US\$ 0,92)	(ZAR 2,59) US\$ 0,25	ZAR 3,76 (US\$ 0,36)	2.58
Lamivudine (150mg)	ZAR 10,67 (US\$ 1,02)	(ZAR 1,46) US\$ 0,14	ZAR 2,66 (US\$ 0,25)	4.01
AZT/lamivudine (300mg/150mg)	ZAR 13,33 (US\$ 1,27)	(ZAR 3,81) US\$ 0,36	ZAR 5,94 (US\$ 0,57)	2.24
Nevirapine (200mg)	ZAR 6,00 (US\$ 0,57)	(ZAR 2,39) US\$ 0,23	ZAR 3,49 (US\$ 0,33)	1.72

**Table 5: COMPARISON BETWEEN PRICE CHARGED AND ECONOMIC VALUE:
PAEDIATRIC FORMULATIONS**

Product	Price charged to private sector	WHO pre- qualified generic	Estimated economic value	Ratio: private sector to economic value
AZT (50mg/5ml solution)	ZAR 69,06 (US\$ 6,58)	(ZAR 21,00) US\$ 2,00	ZAR 30,45 (US\$ 2,90)	2.27
Lamivudine (10mg/ml solution)	ZAR 97,92 (US\$ 9,33)	(ZAR 27,30) US\$ 2,60	ZAR 49,69 (US\$ 4,73)	1.97

67. In arriving at estimates of the respondents' manufacturing costs (these being the costs of the international companies), it would have been appropriate in respect of each ARV to take the price charged by generic manufacturers and to subtract the generic rate of profit. However, the complainants do not have access to information about the generic rate of profit. For this reasons, the estimates of manufacturing costs relied upon do not subtract the generic rate of profit. To repeat: the prices charged for generics have been adopted as an indicator of generic manufacturing costs. This method of calculation is generous to the respondents. (See the affidavit of Alexander Marius van den Heever, **Expert Affidavit AVDH**).
68. On top of this, allowance for R&D costs, licensing fees and profit have been added. The higher than average profit norm which is used includes a profit premium for innovation. Moreover, because no deduction was made for generic profits, the allowance made for profit is an extremely generous one. As a result the true ratio between the prices actually charged and the economic value of the goods is probably significantly higher than what is reflected in the last column of both Tables 4 and 5. In addition no account is taken of profit achieved to date, which would have enabled many if not all of the R&D costs to have been recovered by this time. Nor is account taken of the volume-related reduced average cost that would result if the drugs were made available to all people with HIV/AIDS. See in this regard, paragraphs 21 to 25 of the affidavit of Alexander Marius Van Den Heever annexed marked **Expert Annexure AVDH**.

Information used in determining estimates of "economic value"

69. In its financial results for 2001, GlaxoSmithKline reports global sales of pharmaceutical products to the value of US\$24 775 million, with R&D costs amounting to US\$3 679 million, or 14.85% of sales. This is reflected in GlaxoSmithKline's 2001 Financial Report, a summary of which is annexed as **Annexure Q**. The financial reports can be sourced at www.gsk.com/financial/reports.html.
70. On the basis of a 16.2% average return on revenues for the global pharmaceutical

industry and an expenditure of 14.85% of sales on R&D, together amounting to 31.05% of sales, the economic value for Retrovir® can be estimated according to the following formula: estimated economic value = 1.45 × estimated manufacturing cost. In regard to how this formula is reached see the affidavit of Jonathan Michael Berger annexed as **Annexure JMB**.

71. The estimated economic value for 3TC® also includes the cost of royalty payments. Therefore it is calculated according to the following formula: estimated economic value = 1.82 × estimated manufacturing cost. In this regard see the affidavit of Jonathan Michael Berger annexed as **Annexure JMB**.
72. The estimated economic value for the fixed-dose combination of Combivir® includes the cost of royalty payments in respect of one component of this drug. Therefore it is calculated according to the following formula: estimated economic value = 1.56 × estimated manufacturing cost. In regard to how this formula is reached, see the affidavit of Jonathan Michael Berger annexed as **Annexure JMB**.
73. In its financial results for 2001 Boehringer-Ingelheim reports global sales to the value of €6 694 million, with R&D costs amounting to €1 019 million, or 15.2% of sales. In this regard see Boehringer-Ingelheim's 2001 Financial Report, a summary of which is annexed as **Annexure S**, and which was obtained from www.boehringer-ingelheim.com/corporate/corp/sr2001/corp_fin_high.htm.
74. On the basis of a 16.2% average return on revenues for the global pharmaceutical industry and an expenditure of 15.2% of sales on R&D, together amounting to 31.4% of sales, the estimated economic value for Viramune® can be estimated according to the following formula: estimated economic value = 1.46 × estimated manufacturing cost. In regard to how this formula was reached, see the affidavit of Jonathan Michael Berger annexed as **Annexure JMB**.
75. In the case of Viramune®, the average costs of R&D appear to have been borne by Boehringer-Ingelheim itself. This is not the case with Retrovir®, 3TC® and Combivir®.

This is dealt with further below.

76. The complainants contend that the pricing analysis above indicates a strong *prima facie* case that the respondents are charging excessive prices to the detriment of consumers for the ARVs in question, as there is no reasonable relation between the prices charged to the private sector and the economic value of each particular ARV. This is particularly so given the various assumptions in the reasoning that generously favour the respondents.
77. A more precise pricing analysis is only possible if the respondents provide relevant information to the Commission. The complainants have made full allowance for creating incentives to innovate in the pharmaceutical sector in their pricing analysis, because they do not wish to deny a benefit properly related to the costs of R&D actually incurred in the development and bringing to market of socially beneficial products.
78. While the complainants have not been able to rely on the actual costs of R&D borne by the relevant manufacturing respondents but rather upon estimates it is nevertheless necessary to draw attention to the extent to which public funding contributed towards the costs of R&D in respect of the drugs that are the subject of this complaint. The Commission during the course of its investigations is invited to require the respondents to disclose the actual R&D costs incurred.

Retrovir[®]

79. The R&D history of AZT is referred to by James Packard Love in an affidavit annexed as **Expert Annexure JPL**. The following paragraphs summarise the most relevant aspects of this history.
80. AZT was initially synthesized in 1964 by Dr Jerome Horowitz of the Michigan Cancer Foundation, under a grant from the National Cancer Institute (NCI). In 1974, Wolfram Ostertag of the Max Planck Institute demonstrated the effect of AZT on animal retroviruses, using a mouse retrovirus in a test tube.

81. Working with staff at Duke University, staff of the NCI (none of whom were employees of GlaxoSmithKline or any of its predecessors) developed and provided the first application of the technology for determining whether a drug like AZT can suppress HIV in human cells, as well as the technology to determine at what concentration such an effect might be achieved in humans. These researchers were also the first to administer AZT to a human being with AIDS, and the first to perform clinical pharmacology studies in patients. In addition, they also performed the immunological and virological studies necessary to infer that the drug might work and was therefore worth pursuing in further studies.
82. It was on the back of this well-developed research that Burroughs Wellcome (BW), now GlaxoSmithKline, managed to receive marketing approval from the Food and Drug Administration (FDA) for AZT on 19 March 1987. Designated at the time as an orphan drug (one that targets a disease that affects less than 200 000 people), BW was entitled to receive a tax credit of 50% of the costs incurred by conducting US clinical trials.
83. On the basis of tax credits obtained, the average costs incurred by conducting clinical trials for an orphan drug for the period 1983-1993 have been determined to be US\$3.79 million (US\$3.2 million in 1995 dollar terms), or ZAR39 795 000. There is no reason to believe that the costs of trials for AZT would have differed in any significant respect from this amount.
84. This amount is a cost per drug approval, which includes the clinical trial costs of those orphan drugs that never received FDA approval. Approximately one in five orphan drugs make it to market, in line with all drugs entering phase one clinical trials that have a 20% chance of reaching the market.
85. In the 2002 financial year, sales of AZT in South Africa amounted to ZAR9 251 000 or 1.1% of total world sales of US\$80 million or ZAR840 million. On the basis that the costs of R&D to be attributed to South Africa are determined by the ratio of South African to worldwide sales, the costs to GSK or its supplier of developing AZT amount to approximately ZAR438 000, or approximately 4.7% of sales for the 2002 financial year

(a single financial year).

86. In July 2002 a search was conducted on behalf of the complainants to establish the extent of public funding of clinical trials that are currently taking place involving the use of registered ARVs. A search was conducted for each of the four ARVs that is the subject of the complaint. The web-based database which was used provides easy access to information on US-based clinical trials for a wide range of diseases and conditions, including HIV/AIDS. This information was obtained from the following web site: www.ClinicalTrials.gov. For the sake of convenience the results of the search are annexed hereto. The AZT search is annexed marked **Annexure T**. The lamivudine search is annexed marked **Annexure U**, the AZT/lamivudine search is annexed marked **Annexure V** and the nevirapine search is marked **Annexure W**.
87. The AZT search indicates that of 21 current clinical trials involving AZT, not a single one is wholly sponsored by a private firm. Only one trial is being co-sponsored by the US National Institute of Allergy and Infectious Diseases (NIAID) and three private firms, including Glaxo Wellcome (GW) – GlaxoSmithKline was formerly Glaxo Wellcome. Of the remaining 20 trials, 15 are wholly sponsored by the NIAID, with the other five being sponsored by a range of public health institutes or publicly funded health institutes.

3TC[®]

88. Lamivudine was initially discovered and patented for the treatment of HIV/AIDS by BioChem Pharma, a Canadian corporation that has since merged with Shire Pharmaceuticals Group plc (Shire). GlaxoSmithKline (through its international companies) holds the exclusive rights to develop, manufacture, market and sell lamivudine outside of Canada in return for a 14% royalty fee. Within Canada, Shire and GlaxoSmithKline have formed a commercialised partnership. While certain aspects of the licensing agreement are widely known, the complainants are not in possession of a copy of the agreement.
89. According to the search conducted for the complainants referred to above (the results of which are annexed as **Annexure U**), of the 26 current clinical trials involving lamivudine,

only two are wholly sponsored by private firms, with another being co-sponsored by the NIAID and GW and a further trial being co-sponsored by the NIAID and three private firms, including GW. Of the remaining 22 trials, 20 are wholly sponsored by the NIAID, with the other two being sponsored by a range of federal health institutes.

Combivir[®]

90. It was on the back of the research in respect of AZT and lamivudine that the development of the fixed-dose ARV Combivir[®] was possible. According to the search conducted for the complainants referred to above (the results of which are annexed as **Annexure V**), eight current clinical trials involving AZT/lamivudine can be identified. The US federal government is sponsoring all of these, with six being wholly sponsored by the NIAID and one of which is co-sponsored by the NIAID and three private firms, including GW.

Viramune[®]

91. According to the search conducted for the complainants referred to above (the results of which are annexed as **Annexure W**) nine current clinical trials involving nevirapine can be identified, all of which are wholly sponsored by the US federal government sponsored, including six wholly sponsored NIAID clinical trials.

Profiteering in the pharmaceutical sector

92. Despite repeated claims that investment in pharmaceutical R&D is a high-risk activity, the facts paint a somewhat different picture. Whether measured in terms of return on revenue or on assets, the global pharmaceutical industry consistently outperforms every other sector. The figures for 2001, for example, are telling.

93. On the basis of return on revenues, the pharmaceutical industry tops the Fortune Global 500 list with 16.2%, substantially higher than the second placed industry (diversified financials) at 11.6% and the third placed industry (beverages) at 9.7%. The average return on revenues for the top ten industries is only 7.92%.

94. A few other comparisons are instructive. The chemicals industry recorded a 4% return

on revenues, with health care recording 3.3%, insurance 1.9%, food and drug stores 1.7% and health care wholesalers 1.3% return on revenues respectively.

95. On the basis of return on assets, the pharmaceutical industry once again tops the Fortune 500 list with 14%, substantially higher than the second placed industry (beverages) at 9.7% and the third placed industry (household and personal products) at 8.6%. The average return on assets for the top ten industries is only 6.35%. In this regard see “The 2002 Global 500: Top Performing Companies and Industries (Industries: Return on Assets)”, published in Fortune Magazine, 22 July 2002. An extract taken from www.fortune.com/lists/G500/g500_topperf_ind_returnass.html is annexed marked **Annexure X**.
96. On the basis of return on assets, the health care industry recorded a 4.3% return, with chemicals recording 3.9%, health care wholesalers 3.2%, food and drug stores 3.1% and insurance 0.4% return on assets respectively.
97. Unlike many other industries, however, ordinary market forces do not control the pharmaceutical sector. This complaint and supporting documents demonstrate that ARVs cannot be substituted for each other. It cannot be expected of consumers to accept less satisfactory treatment when the particular products of the respondents are prescribed and required for life and where patent protection precludes access to generics. It is in this context that detriment to consumers and the reasonableness of prices charged must be assessed.
98. Once it is established that the respondents are charging excessive prices to the detriment of consumers as contemplated by section 8(a) of the Act, it does not matter that elsewhere in the world higher prices for the ARVs in question are charged. A contravention of section 8(a) has been *prima facie* established by the complainants analysis and supporting documents. An investigation by the Commission using its investigative powers and procedures under the Act will, we submit, further substantiate the complaint.

CONSOLIDATION OF COMPLAINTS

99. With regard to excessive pricing of ARVs the complainants are aware of the complaint already filed by Cipla-Medpro (Pty) Ltd (Cipla-Medpro) on 4 October 2001 against several of the respondents. While in respect of excessive pricing of ARVs there is some degree of overlap, the present complaint seeks relief in the public interest more broadly. In addition, the evidence produced and arguments made in this complaint go significantly beyond those in the Cipla-Medpro complaint. Nevertheless, at the heart of both complaints lie allegations of prohibited abuse of dominance through excessive pricing carried on under the protective monopoly of patent rights.
100. In terms of rule 17(2) of the Competition Commission Rules (Rules for the Conduct of Proceedings in the Competition Commission, Government Notice No. 22025, Government Gazette 428, 1 February 2001), two or more complaints may be consolidated “under a common investigation if they concern the same firm as potential respondent.” This is indeed the case here. In the result, we submit that this complaint and the Cipla-Medpro complaint be consolidated under a common investigation.
101. Neither this Statement of Complaint nor any of the information submitted with it is in any way confidential.
102. The complainants offer to assist the Commission to the best of their ability by gathering and furnishing any information that the Commission may require to investigate the complaint. The experts who have assisted the complainants similarly are willing to be contacted for further information. The complainants request that any communication with them be directed through their legal representatives, the AIDS Law Project. The complainants also request that their legal representatives be informed of any communication with the experts who have deposed to affidavits in relation to this complaint.

RELIEF SOUGHT

103. The complainants request after investigation in due course, that the Commission refer

this complaint to the Competition Tribunal in terms of section 50(2)(a) of the Act, with the referral including “all the particulars of the complaint as submitted by the complainant”, in terms of section 50(3)(a)(i). In terms of the express provisions of section 58 of the Act, upon a finding of prohibited excessive pricing the Tribunal may—

- order that the excessive pricing practices stop (section 58(1)(a)(i));
- declare the conduct to be a prohibited practice for purposes of damages claims by all persons who can establish that they have suffered loss or damage as a result of the prohibitive practice concerned (section 58(1)(a)(v) read with section 65); and
- impose an administrative penalty (section 58(1)(a)(iii)).

104. Upon referral, the complainants request that the Commission recommend that the Tribunal makes orders in terms of all the above provisions.

105. As regards an administrative penalty, section 59(2) of the Act provides that a maximum of “10 per cent of the firm’s annual turnover in the Republic and its exports from the Republic during the firm’s preceding financial year” may be imposed.

106. To be an effective remedy, the relief granted must act to prevent this type of prohibited conduct from recurring. Thus a mere declaration that the conduct constitutes prohibited excessive pricing, even if coupled with an order to reduce prices, is not enough. The message sent out by such relief is that it is better to charge excessive prices and wait for action to be taken than to voluntarily lower prices. If the end result is merely to be forced to drop prices, the rational response may be to continue making profits and run the risk of an adverse costs order. In short, any relief that is not punitive in nature will not be an effective remedy.

107. In addition, TAC and its allies have engaged in a sustained and well-publicised campaign for nearly four years to ensure that the respondents either reduce prices of ARVs to generic product levels or allow generic competition by granting non-exclusive voluntary licenses on reasonable terms. The failure of the respondents to do either has led to premature, predictable and avoidable loss of life. Any relief must take these factors into account.

108. In all the circumstances the imposition of an administrative penalty would be fully justified. The fact that the Act treats administrative penalties as an appropriate form of relief following a finding of prohibited excessive pricing, even when the prohibited practice is a first offence, shows that such conduct is regarded as a particularly egregious contravention of the Act.
109. The complaint has been filed on behalf of all the complainants by the AIDS Law Project (ALP). The ALP will accept service of all documents on behalf of the complainants related to this complaint. The ALP is situated at the Centre for Applied Legal Studies, 1st Floor: D J du Plessis Building, University of the Witwatersrand: West Campus, Yale Road, Braamfontein, Johannesburg. The ALP can be contacted at (011) 717-8600 (T) and (011) 403-2341(F).
110. The Commission will appreciate that it has required some time for the complainants to compile the information required to submit this complaint, and that its resolution may be a life or death matter for the many people who are affected. In the circumstances the complainants urge that it be treated with the priority that it deserves.
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