

## **SETTLEMENT AGREEMENT**

entered into between, on the one hand,

**the twelve COMPLAINANTS, named below,  
in the complaint submitted by them (“the complaint”)  
to the Competition Commission in South Africa  
in terms of the Competition Act,  
under and in connection with case no 2002Sep226,**

and, on the other hand,

**GLAXOSMITHKLINE SOUTH AFRICA (PTY) LTD,  
GLAXO GROUP LIMITED and THE WELLCOME FOUNDATION  
LIMITED (together defined as “GSK” below).**

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## **INTRODUCTION**

- 1.1. The twelve complainants who are party to this agreement, and are referred to in this agreement as “**the complainants**”, are the following:
  - 1.1.1. **HAZEL TAU**
  - 1.1.2. **NONSIKELELO PATRICIA ZWEDALA**
  - 1.1.3. **SINDISWA GODWANA**
  - 1.1.4. **ISAAC MTHUTHUZELI SKOSANA**
  - 1.1.5. **SR SUSAN ROBERTS**
  - 1.1.6. **DR WILLIAM NKHANGWENI MMBARA**
  - 1.1.7. **DR STEVEN MURRAY ANDREWS**
  - 1.1.8. **DR WILLEM DANIEL FRANCOIS VENTER**
  - 1.1.9. **THE CONGRESS OF SOUTH AFRICAN TRADE UNIONS**
  - 1.1.10. **THE CHEMICAL, ENERGY, PAPER, PRINTING, WOOD AND ALLIED WORKERS’ UNION**
  - 1.1.11. **THE TREATMENT ACTION CAMPAIGN**
  - 1.1.12. **THE AIDS CONSORTIUM.**

It is recorded that **MATOMELA PAUL NGUBANE**, who also submitted a complaint in connection with case no. 2002Sep226, passed away on 16 June 2003.

- 1.2. The complainants and GSK (“**the parties**”) have agreed, and record herein, the terms of settlement upon which the complainants will withdraw against GSK their complaint currently before the Competition Commission.
- 1.3. Throughout this agreement, unless the context indicates otherwise —
  - 1.3.1. **“GSK”** shall mean:

- (a) GLAXOSMITHKLINE SOUTH AFRICA (PTY) LTD (a company incorporated under the laws of South Africa having its registered office at Carisbrook Building, The Campus, 57 Sloane Street, Bryanston 2021, South Africa); and
- (b) GLAXO GROUP LIMITED (a company incorporated under the laws of England having its registered office at Glaxo Wellcome House, Berkeley, Greenford, Middlesex UB6 0NN); and
- (c) THE WELLCOME FOUNDATION LIMITED (a company incorporated under the laws of England having its registered office at Glaxo Wellcome House, Berkeley, Greenford, Middlesex UB6 0NN),

and the expression “GSK company” shall in addition include any affiliated company of any of the three companies named above;

- 1.3.2. **“affiliated company”** in relation to GSK shall mean any corporation, firm, partnership or other entity which is directly or indirectly controlled by, in control of, or under common control with any company included in the definition of “GSK” (and, for the purposes of this definition, “control” shall mean the ability of any entity, whether through ownership of shares or otherwise, to procure that the affairs of another entity are conducted in accordance with its wishes);
- 1.3.3. **“relevant antiretrovirals”** shall mean the chemical compounds known as zidovudine and lamivudine, and shall, subject to 4.3, include all pharmaceutical compositions containing zidovudine and/or lamivudine for the prevention and/or treatment of HIV infection;
- 1.3.4. **“relevant patent(s)”** shall mean all South African patents and patent applications owned by any GSK company which claim any relevant antiretrovirals or any method of manufacture of them or any other aspect of them;

- 1.3.5. “**MCC**” shall mean the Medicines Control Council established under the South African Medicines and Related Substances Act No. 101 of 1965 as amended (“the Medicines Act”), or any successor thereto.

## **GSK’s OBLIGATIONS**

### **2.1. The parties have agreed that GSK:**

- 2.1.1. will without delay extend the voluntary licence granted to Aspen Pharmacare Holdings Ltd (“**Aspen Pharmacare**”), in October 2001, in respect of the public sector to include the private sector;
- 2.1.2. will without delay further extend the voluntary licence granted to Aspen Pharmacare to permit Aspen Pharmacare, subject to any applicable law, to export to sub-Saharan African countries as listed in Annex 1 hereto, relevant antiretrovirals which have undergone any manufacturing or formulation process in South Africa in accordance with the said voluntary licence as extended in terms of 2.1.1;
- 2.1.3. will, within ten (10) days of the date on which this agreement is concluded, offer to grant a voluntary licence with respect to the relevant antiretrovirals to the joint-venture entity of Ranbaxy SA (Pty) Ltd and Adcock Ingram Holdings (Pty) Ltd, namely Thembalami Pharmaceuticals (Pty) Limited (“**Thembalami Pharmaceuticals**”) on terms no less favourable than those granted to Aspen Pharmacare as contemplated in 2.1.1 and 2.1.2;
- 2.1.4. will entertain applications for the grant, on terms no less favourable than the most favourable terms granted to Aspen Pharmacare and/or Thembalami Pharmaceuticals, of two further voluntary licences to other entities, with respect to the relevant antiretrovirals, on the basis that, in

each case respectively — subject to 2.1.7 below where applicable — the applicant meets GSK's standard criteria relating to product quality and reliability, which criteria shall not be more onerous than the criteria which have been met by Aspen Pharmacare and/or Thembalami Pharmaceuticals, and which shall be reasonably applied;

- 2.1.5. will not unreasonably delay, refuse or withhold the grant of a voluntary licence to Thembalami Pharmaceuticals as contemplated in 2.1.3 or to an applicant as contemplated in 2.1.4, and, where the consent of any third party is required for the grant of any voluntary licence referred to in this agreement, GSK undertakes that it and its affiliated companies will use their best endeavours to obtain such consent;
- 2.1.6. undertakes that no GSK company will enforce any relevant patent or any equivalent patent of any GSK company in any of the countries listed in Annex 1 against conduct of a licensee complying with any licence or extension of a licence contemplated in this agreement;
- 2.1.7. will, to the extent that any licensee referred to or contemplated above does not agree, or is at any time unable for any reason beyond its control, to manufacture or formulate relevant antiretrovirals (whether in combination with any other antiretroviral medicines or otherwise) in South Africa, permit the importation of same by such licensee into South Africa, provided that all necessary MCC and other regulatory approvals are obtained, and provided further that no relevant antiretroviral so imported shall be re-exported from South Africa except in accordance with 2.1.2 above;
- 2.1.8. will not require the payment of royalties or similar charges in relation to any of the above licences in excess of five per cent (5%) of the net sales of the relevant antiretrovirals (and for this purpose "**net sales**" shall mean the total amount invoiced or otherwise due (after deduction of all taxes and discounts as shall be agreed between the

licensor and the licensee at the inception of the licence agreement) on sales by the licensee to third parties in terms of the relevant licence) — provided that, where a product sold contains zidovudine and/or lamivudine in combination with one or more other antiretroviral drug(s), the aforesaid maximum of 5% shall be reduced proportionally by means of the formula:

$$\frac{(Z + L)}{(Z + L + X)} \times 5 = \text{applicable maximum \%}$$

where —

- (a) Z = 1 where zidovudine is contained in the product and 0 where zidovudine is not contained in the product;
- (b) L = 1 where lamivudine is contained in the product and 0 where lamivudine is not contained in the product;
- (c) X = the number of other antiretroviral drugs contained in the product

(and, for the avoidance of doubt, it is recorded that the generic equivalent of Combivir<sup>®</sup> would attract a maximum royalty or similar charge of 5% of net sales);

- 2.1.9. will, in the event that any GSK company acquires or allows the acquisition or obtains the grant of any further patent in respect of relevant antiretrovirals which, if it had existed at the time of this agreement, would have been included within the meaning of “relevant patent(s)” as defined in 1.3.4 above or an equivalent patent as contemplated in 2.1.6 above, give effect *mutatis mutandis* to the provisions of 2.1.1 to 2.1.8 above in relation to such patent.

**2.2. The parties record the following:**

- 2.2.1. Nothing in this agreement shall require any GSK company to grant licences under any patents existing outside South Africa and the countries listed in Annex 1.
- 2.2.2. In the event that licensee(s) combine zidovudine and/or lamivudine with any other pharmaceutical compounds, GSK may require such licensee(s) to suitably indemnify GSK against any third party claims including, without limitation, third party claims for patent infringement and product liability.
- 2.2.3. Nothing in this agreement shall be construed as an endorsement by any GSK company of the use of zidovudine and/or lamivudine in combination with any other pharmaceutical compounds where clinical, medical and regulatory approvals to GSK's standards for such combinations have not been obtained.
- 2.2.4. GSK intends, where appropriate and practicable, to endeavour to assist and support the South African government and non-governmental organisations supporting HIV prevention and treatment in South Africa, including in particular the antiretroviral treatment programme in the public sector.
- 2.2.5. It is the view of the complainants that all licensees and applicants for licences contemplated in this agreement should be strongly encouraged, so far as practicable, to manufacture and/or formulate relevant antiretrovirals in South Africa in the interests of developing local pharmaceutical manufacturing capacity and job creation. GSK will accordingly convey this view to all such licensees and applicants for licences. For the sake of clarity, it is recorded that GSK will not delay, refuse or withhold a licence as contemplated above on the basis that the applicant will not agree or will not be able as a licensee to

manufacture or formulate relevant antiretrovirals (whether in combination with other antiretroviral medicines or otherwise) in South Africa.

3. **COMPLAINANTS' OBLIGATIONS**

**The parties have agreed that the complainants**, in return for the obligations undertaken by GSK as set out above, will immediately withdraw the complaint, insofar as it relates to any GSK company, as contemplated by Rule 16(1) of the Rules for the Conduct of Proceedings in the Competition Commission, and immediately forward a copy of the notice of such withdrawal to GSK's legal representatives in South Africa. The complainants acknowledge that such withdrawal means that the complaint is terminated insofar as the complainants are concerned and that the complainants will thereby be precluded from referring the complaint to the Competition Tribunal.

4. **GENERAL**

- 4.1. Each signatory to this settlement agreement represents and warrants that he/she is duly authorised to act on behalf of the complainants or GSK, as the case may be, in entering into this settlement agreement.
- 4.2. This agreement shall be regarded as having been concluded upon the signature of the party whose representative signs last in time.
- 4.3. For the purposes of this agreement, a pharmaceutical composition containing zidovudine and/or lamivudine in combination with any other antiretroviral compound of which any GSK company owns the patent or patent application shall not be included in the definition of "**relevant antiretrovirals**".
- 4.4. Where, in order to give effect to this agreement at any time, it is necessary that any affiliated company do or refrain from doing anything, each of the companies named in the definition of "GSK" shall, without derogating from its own obligations as set out above, use its best endeavours to procure same.

4.5. It is recorded that GSK's standard criteria relating to product quality and reliability referred to in 2.1.4 are set out in a document which has been identified to representatives of the complainants and which is to be held in trust as set out in 4.6.

4.6. It is recorded that attorneys SONNENBERG HOFFMANN GALOMBIK (or, failing them, attorneys designated by the chairperson of the Law Society of the Northern Provinces) will hold in trust for the parties,

4.6.1. a copy of the signed licence agreement referred to in 2.1.1;

4.6.2. a copy of each other signed licence agreement (and extension of a licence agreement) referred to in 2.1.2, 2.1.3 and 2.1.4;

4.6.3. a copy of the document containing GSK's standard criteria, referred to in 4.5,

on terms which have been agreed in writing between the parties prior to the conclusion of this agreement.

4.7. No party may cede any right or delegate any obligation provided for in this agreement without the written consent of the others.

4.8. This agreement shall be governed by and construed in accordance with South African law, and, insofar as may be necessary to render effective the jurisdiction of the High Court of South Africa, GSK hereby submits to such jurisdiction in relation to this agreement.

Thus done and signed at

on

**Witness:**

**Signed on behalf of GSK by:**

Full name:

Full name:

Designation:

Signature: .....

Signature: .....

Thus done and signed at

on

**Witness:**

**Signed on behalf of the complainants  
by:**

Full name:

Full name:

Designation:

Signature: .....

Signature: .....