

## **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,

**BOEHRINGER INGELHEIM (PROPRIETARY) LIMITED,  
INGELHEIM PHARMACEUTICALS (PROPRIETARY) LIMITED,  
BOEHRINGER INGELHEIM GmbH,  
BOEHRINGER INGELHEIM PHARMACEUTICALS INC,  
BOEHRINGER INGELHEIM PHARMA KG,  
BOEHRINGER INGELHEIM INTERNATIONAL GmbH and  
DR KARL THOMAE GmbH**

**(together defined herein below as “BOEHRINGER INGELHEIM”).**

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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. **NONTSIKELELO 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 **BOEHRINGER INGELHEIM** (“**the parties**”) have agreed, and record herein, the terms of settlement upon which the complainants will withdraw against **BOEHRINGER INGELHEIM** their complaint currently before the Competition Commission.
- 1.3. Throughout this agreement, unless the context indicates otherwise —
- 1.3.1. “**BOEHRINGER INGELHEIM**” shall mean:
    - (a) Boehringer Ingelheim (Proprietary) Limited (a company incorporated under the laws of South Africa under Registration No. 1966/008619/07, having its registered office at 404 Main Avenue, Ferndale Randburg, Gauteng, South Africa); and

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- (b) Ingelheim Pharmaceuticals (Proprietary) Limited (a company incorporated under the laws of South Africa under Registration No. 66/08618/07, having its registered office at 404 Main Avenue, Ferndale Randburg, Gauteng, South Africa); and
  - (c) Boehringer Ingelheim GmbH (a company incorporated under the laws of Germany, having its registered office at 173 Binger Strasse, 52216 Ingelheim am Rhein, Germany); and
  - (d) Boehringer Ingelheim Pharmaceuticals Inc (a company incorporated under the laws of the United States of America, having its registered office at 900 Ridgebury Road, P.O. Box 368, Ridgefield, CT 06877, USA); and
  - (e) Boehringer Ingelheim Pharma KG (a company incorporated under the laws of Germany, having its registered office at 173 Binger Strasse, 52216 Ingelheim am Rhein, Germany); and
  - (f) Boehringer Ingelheim International GmbH (a company incorporated under the laws of Germany, having its registered office at 173 Binger Strasse, 52216 Ingelheim am Rhein, Germany); and
  - (g) Dr Karl Thomae GmbH (a company incorporated under the laws of Germany, having its registered office at 173 Binger Strasse, 52216 Ingelheim am Rhein, Germany),

and the expression “**Boehringer Ingelheim company**” shall in addition include any affiliated company of any of the companies named above;

- 1.3.2. “**affiliated company**” in relation to **BOEHRINGER INGELHEIM** 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 “**BOEHRINGER INGELHEIM**” (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 antiretroviral(s)**” shall mean the chemical compound known as nevirapine, and shall include all pharmaceutical compositions containing nevirapine 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 **Boehringer Ingelheim company** at or before the time of conclusion of this agreement which claim any relevant antiretrovirals or any method of manufacture of them or any other aspect of them, and for the purposes of this definition South African patent applications shall include any international application made at or before the time of conclusion of this agreement in terms of the Patent Cooperation Treaty of 19 June 1970, as amended and in force in South Africa, that designates the Republic of South Africa;
- 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.

## 2. **BOEHRINGER INGELHEIM’s OBLIGATIONS**

### **The parties have agreed that BOEHRINGER INGELHEIM:**

- 2.1. will use its best endeavours to bring about the conclusion, without delay, of an agreement granting a voluntary licence in respect of relevant antiretroviral(s) to Pharmacare Limited (a company incorporated under the laws of South Africa under Registration No. 1898/000252/06) or to another appropriate company in the Aspen Pharmacare group, on terms no less favourable to the licensee than the terms contained in the draft licence agreement referred to in 4.4;
- 2.2. will agree to the grant, without any unreasonable delay and on terms no less favourable than the most favourable terms offered or granted (as the case may be) as contemplated in 2.1, of two further voluntary licences to other entities which are entitled to hold medicinal product registrations granted by the MCC, with respect to the relevant antiretroviral(s), on the basis that, in each case respectively — subject to 2.3.5 below where applicable — the applicant meets **BOEHRINGER**

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**INGELHEIM'S** standard criteria for the selection of nevirapine licensees, which criteria shall not be more onerous than the criteria which have been met by Pharmacare Limited (or are met by another company in the Aspen Pharmacare group, as the case may be), and which shall be reasonably applied;

2.3. in relation to any voluntary licence granted as contemplated in 2.1 and 2.2 (and notwithstanding anything to the contrary that may be contained in the draft licence agreement referred to in 2.1 and 4.4) —

2.3.1. will ensure that such licence extends to both the public and private sectors;

2.3.2. 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) on sales by the licensee to third parties in terms of the relevant licence) — provided that, where a product sold contains nevirapine in combination with one or two or more other antiretroviral drug(s), the aforesaid maximum of 5% shall be reduced proportionally, i.e. to 2.5%, 1.66%, etc., as the case may be;

2.3.3. will permit the licensee to export to the 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;

2.3.4. confirms that the effect of the licence granted is that no **Boehringer Ingelheim company** will be entitled to enforce any relevant patent or any equivalent patent of any **Boehringer Ingelheim Company** in any of the countries listed in Annex 1 against conduct of a licensee complying with any licence contemplated in this agreement, but this acknowledgement and undertaking shall not be read to convey or to imply that any **Boehringer Ingelheim company** supports or encourages or endorses the combination into a

single administration form of the relevant antiretroviral(s) with any other antiretroviral medicines, and such combinations, if made, will be made exclusively on the initiative of the licensee and on its own risk;

- 2.3.5. will, at least to the extent that any licensee referred to or contemplated above does not agree, or is at any time unable, 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 2.3.3 above;
- 2.4. will strongly encourage all licensees to manufacture and/or formulate relevant antiretroviral(s) in South Africa in the interests of developing local pharmaceutical manufacturing capacity and job creation, but will not delay, refuse or withhold any voluntary licence referred to in this agreement 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;
- 2.5. will, in the event that the consent of any third party is required for the grant of any voluntary licence referred to in this agreement, use its best endeavours to obtain such consent.

### 3. **COMPLAINANTS' OBLIGATIONS**

**The parties have agreed** that the complainants, in return for the obligations undertaken by **BOEHRINGER INGELHEIM** as set out above, will immediately withdraw the complaint insofar as it relates to any **Boehringer Ingelheim 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 **BOEHRINGER INGELHEIM'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 the respective companies of **BOEHRINGER INGELHEIM**, 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. 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 "**BOEHRINGER INGELHEIM**" shall, without derogating from its own obligations as set out above, use its best endeavours to procure same.
- 4.4. It is recorded that the draft licence agreement referred to in 2.1 is a document bearing the heading "20031127 BIZA PHARMACARE DRAFT LICENCE AGREEMENT" and consists of 29 numbered pages plus appendices A, B, C, I (glossary) and II (contact persons and addresses) consisting of a further 38 pages. A copy of this document has been provided to representatives of the complainants, and is to be held in trust as set out in 4.6.
- 4.5. It is recorded that **BOEHRINGER INGELHEIM'S** standard criteria referred to in 2.2 are set out in a document, a copy of which has been provided 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 draft licence agreement referred to in 2.1 and 4.4;

4.6.2. a copy of each concluded licence agreement, when signed, which is referred to in 2.1 and 2.2;

4.6.3. a copy of the document containing **BOEHRINGER INGELHEIM'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, **BOEHRINGER INGELHEIM** hereby submits to such jurisdiction in relation to this agreement.

4.9. It is noted that **BOEHRINGER INGELHEIM** intends, where its products are being used and where 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.

Thus done and signed at

on

**Witness:**

**Signed on behalf of BOEHRINGER  
INGELHEIM (PROPRIETARY) LIMITED  
and INGELHEIM PHARMACEUTICALS  
(PROPRIETARY) LIMITED by:**

Full name:

Full name:

Designation:

Signature: .....

Signature: .....

Thus done and signed at

on

**Witness:**

**Signed on behalf of  
BOEHRINGER INGELHEIM GmbH,  
BOEHRINGER INGELHEIM  
PHARMACEUTICALS INC,  
BOEHRINGER INGELHEIM PHARMA KG,  
BOEHRINGER INGELHEIM  
INTERNATIONAL GmbH and  
DR KARL THOMAE GmbH 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: .....