

NON ASSERT Declaration  
("Declaration")

by

**BOEHRINGER INGELHEIM INTERNATIONAL GMBH**  
**BINGER STRABE 173**  
**55216 INGELHEIM AM RHEIN**  
**GERMANY**

(hereinafter referred to as "BI")  
duly herein represented by

[ ] and [ ]

in their capacity as authorised signatories of BI

TO

**COMPANY**

[Insert Address]

(hereinafter referred to as "Company")

duly herein represented by

[.....]

**§ 1 INTRODUCTION**

- 1.1 **WHEREAS** BI is entitled to declare on its behalf and on behalf of the Patentees to refrain from suing Company under Patentees Patent(s) in Territory.
- 1.2 **WHEREAS** Company seeks protection against a lawsuit based on the Patent(s) to perform the activities provided for herein.
- 1.3 **WHEREAS** the purpose of this Declaration is to improve the supply of the continent of Africa and all Least Developed Countries and/or Low Income Countries with nevirapine containing pharmaceuticals.

**§ 2 DEFINITIONS**

In this Declaration, including Annex 1 and Annex 2,

**Patent(s)** – shall mean one or more rights listed in Annex 1. Patent(s) may be granted patent(s) or pending patent application(s).

**Patentee** – shall mean the patentee or patentees of Patent(s) as disclosed in the respective patent register.

**WHO pre-qualification list** – refers to the list "Access to HIV/AIDS Drugs and Diagnostics of Acceptable Quality", 46<sup>th</sup> Edition, January 18, 2007, or to a subsequent Edition thereof, available at the WHO, *see*, for instance, <http://mednet3.who.int/prequal>.

**Product** – shall mean a pharmaceutical composition that fulfils all the following conditions (i) to (v):

- (i) The composition contains the active ingredient nevirapine, or salts or solvates of nevirapine, in a form ready for the administration to human beings.
- (ii) The composition must be packed to allow storage.

- (iii) The Packaging Material must be labelled to allow easy identification of manufacturer and medicament. Furthermore, either Packaging Material or End-User Packaging must identify the country or countries for which the pharmaceutical composition is intended.
  - (iv) The composition must be listed in the WHO pre-qualification list.
  - (v) The composition must fall within the scope of the claim(s) of Patent(s).
- Product may contain besides nevirapine or salts or solvates of nevirapine also other active ingredient(s).

**Packaging Material** – shall mean a containment device that allows storage and distribution of Product.

**End-User Packaging** – shall mean packed Product as it is intended to be delivered to the end-user.

**Package Insert** – shall mean instructions for the medical professional or end-user of the Product.

**Territory** - shall mean those countries which either qualify as being a sovereign state of the continent of Africa and/or a Least Developed Country (according to UNDP's definition of Least Developed Countries) and/or a Low Income Country (according to the World Bank definition); *see* Annex 2 for the complete list.

**Patent Territory** – shall mean the those countries under Territories where BI holds Patent(s) which are: Botswana, Gambia, Ghana, Kenya, Lesotho, Malawi, Sudan, Swaziland, Uganda, Zambia, Zimbabwe, Benin, Burkina Faso, Cameroon, Central African Republic, Chad, Congo, Gabon, Guinea, Ivory Coast, Mali, Mauritania, Niger, Senegal, Togo, South Africa, Egypt, India, Pakistan, Uzbekistan, Vietnam, Nigeria.

### § 3. **MARKETING, SUPPLY AND DISTRIBUTION**

- 3.1 Company, when marketing, selling and distributing Product, does not make any reference to the product or trademark VIRAMUNE<sup>®</sup> or any other product or trademark of BI.
- 3.2 Company incorporates on Packaging Material or End-User Packaging of Product, the statement "*Solely for use in*" followed by the name of one or more of the states of Patent Territory for which Product is intended to be marketed.
- 3.3 Company ensures that Product and especially the Packaging Material of Product is easily visually distinguishable from the original product VIRAMUNE<sup>®</sup> of BI.
- 3.4 Company manufactures Product in compliance with the information as to (i) strength, (ii) dosage form, (iii) manufacturing site as set forth in the WHO pre-qualification list.

### § 4. **NON ASSERT**

- 4.1 As long as the conditions under § 3 are met, BI hereby declares not to enforce Patent(s) in Patent Territory against Company in respect of offering, and/or putting on the market, and/or using Product, and/or importing or stocking Product for supply of Territory.
- 4.2 Enforcement of the Patent(s) for any activity outside of Territory is reserved.
- 4.3 This declaration does not cover any acts of manufacture.
- 4.4. Nothing in this Declaration shall be construed as granting to Company any rights in respect of any pharmaceutical product registration vesting in BI.

**§ 5. OPTION TO A MANUFACTURING LICENSE**

For WHO approved manufacturing sites BI offers an option for a royalty free license for the manufacture of Product for supply within Territory under conditions to be specified separately if needed by Company for the purpose of this Declaration.

**§ 6. VALIDITY, CHALLENGE, MAINTENANCE AND INFRINGEMENT**

- 6.1 Company is fully responsible to comply with the local law including product safety reporting to regulatory authorities.
- 6.2 BI rejects any liability or claims arising from activities by Company as a result of the Declaration.
- 6.3 BI shall not be under any obligation to maintain Patent(s). Furthermore, BI is neither obliged to monitor the status of the Patent(s) nor to inform Company if BI becomes aware that the status has changed.

**§ 7. DURATION, NOTIFICATION**

- 7.1 This Declaration will take effect from the date of receipt by BI of a duly signed letter of Company confirming receipt of this Declaration.
- 7.2 In case Company does not meet the provisions of § 3, BI reserves its right to withdraw this Declaration with immediate effect. In such case BI will use reasonable efforts to serve notice of such withdrawal to Company. Therefore Company shall at all times keep BI informed on its mailing address.

THIS DONE AND SIGNED AT \_\_\_\_\_ ON THIS THE \_\_\_\_ DAY  
OF \_\_\_\_\_

For and on behalf of  
Boehringer Ingelheim International GmbH,  
[ ] and [ ],  
warranting by their signature  
that they are duly authorised hereto  
ppa.

## Annex 1: Patent(s) Encompassed by the Declaration

### Annex 1A Nevirapine compound patents / pending applications

Country		Status	Filing No	Patent No	Filing Date	Grant date	Expiry date, (noncommittal)
AP	African Regional Industrial Property Organization (ARIPO) <sup>1</sup>	granted	AP/P/90/00224	AP179	11/16/90	4/30/92	11/16/10
NG	Nigeria	granted	238/90	13374	11/16/90	2/22/00	11/16/10
OA	African IP Organization (OAPI) <sup>2</sup>	granted	59896	9852	11/16/90	8/15/94	11/16/10
ZA	South Africa	granted	90/9246	90/9246	11/19/90	7/29/92	11/19/10

### Annex 1B Nevirapine hemihydrate patents / pending applications

Country		Status	Filing No	Patent No	Filing Date	Grant date	Expiry date, (noncommittal)
EG	Egypt	pending	983/98		8/23/98		
IN	India	pending	2485/Del/98		8/24/98		
PK	Pakistan	pending	870/98		8/24/98		
UZ	Uzbekistan	granted	IAP-2000-0194	IAP02502	8/11/98	9/28/04	8/11/18
VN	Vietnam	granted	1-2001-00948	2478	8/11/98	11/25/01	8/11/18
VN	Vietnam	granted	1-2000-0236	2431	8/11/98	11/19/01	8/11/18
ZA	South Africa	granted	98/7623	98/07623	8/24/98	3/22/00	8/24/18

## Annex 2: Countries of Territory

Afghanistan, Angola, Bangladesh, Benin, Bhutan, Burkina Faso, Burundi, Cambodia, Cape Verde, Central African Republic, Chad, Comores, Congo (DR), Djibouti, Equatorial Guinea, Eritrea, Ethiopia, Gambia, Guinea, Guinea-Bissau, Haiti, Kiribati, LAO PDR, Lesotho, Liberia, Madagascar, Malawi, Maldives, Mali, Mauritania, Mozambique, Myanmar, Nepal, Niger, Rwanda, Samoa, Sao Tome and Principe, Senegal, Sierra Leone, Solomon Islands, Somalia, Sudan, Tanzania, Timor-Leste, Togo, Tuvalu, Uganda, Vanuatu, Yemen, Zambia, Cote d'Ivoire, Ghana, India, Kenya, Democratic People's Republic of Korea (DR), Kyrgyz Republic, Mongolia, Nigeria, Pakistan, Papua New Guinea, Tajikistan, Uzbekistan, Vietnam, Zimbabwe, Algeria, Botswana, Cameroon, Congo (ROC), Egypt, Gabon, Libya, Mauritius, Morocco, Namibia, Seychelles, South Africa, Swaziland, Tunisia.

<sup>1</sup> ARIPO: Botswana, Gambia, Ghana, Kenya, Lesotho, Malawi, Sudan, Swaziland, Uganda, Zambia and Zimbabwe

<sup>2</sup> OAPI: Burkina Faso, Benin, Central African Republic, Congo, Côte d'Ivoire, Cameroon, Gabon, Guinea, Mali, Mauritania, Niger, Senegal, Chad, Togo