MEMORANDUM OF UNDERSTANDING

Between
Essential Patent Pool for AIDS (EPPA)
and
the Minister of Health on behalf of Country "A"

1 Purpose

1.1 This Memorandum of Understanding (MoU) establishes an arrangement between the Essential Patent Pool for AIDS (EPPA), a non-profit corporation established under the laws of (Need to designate EPPA country of organization,) and the Minister of Health, on behalf of the Country "A".
1.2 This arrangement establishes a co-operative relationship between the parties in connection with the collective management of patents relating to essential medical technologies.

2 Findings

2.1 The cost of essential medicines in Country "A" is a barrier to providing access to medicines for all.
2.2 Patents on essential medical inventions restrict innovation and adaptation of medicines and devices to fit the needs of patients such as different formulations, combinations, dosages and medicine forms. Innovation and adaptation is necessary to cope with the differing viral strains, changing immunities, related infectious diseases, local health system conditions and local patient customs, and to enhance patient compliance with treatment regimes.
2.3 Patients suffering from AIDS benefit from an efficient competitive global market for essential medical products used in the treatments of AIDS, and economies of scale and access to manufacturing know-how are important for for efficient manufacturing of essential medical treatments and devices.
2.4 The multitude of patents, potential claims of infringement, the variance of national laws, the complexity of international treaties and national patent laws, and patent restrictions on the export of essential medical technologies have presented barriers for access to medicine for all.
2.5 [If a WTO Member] The November 14, 2001 WTO Doha Declaration on TRIPS and Public Health states in paragraph 4 that intellectual property rules "should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all."
2.6 The establishment of a essential patent pool for AIDS will alleviate the problems in the development and delivery of essential medical treatments and devices for persons suffering from AIDS [if a WTO Member], and will help meet the obligations of paragraph 4 of the Doha Declaration on TRIPS and Public Health.

3 Co-operation

3.1 The parties intend to actively maintain a co-operative relationship in order to enhance the efficient and effective delivery of health care for patients with HIV/AIDS.
3.2 Country "A" will secure written agreements with all necessary government agencies and departments to co-operate to implement this MoU.

4 Access to and exchange of information

4.1 The parties intend that each will provide to the other, on request in writing, copies of information that might assist the other party to carry out its functions.
4.2 The provision of information is subject to statutory provisions as they apply to each agency restricting access to confidential information. To the extent that these statutory provisions allow or require, any confidential information provided under paragraph 4.1 will be provided to the other party on a confidential basis. Each party will keep confidential any such information provided by the other party, and will not release it to any person other than members of its organization who need to know the information for work purposes, except with the agreement of the owner of the information or the written consent of the disclosing party.
4.3 This MoU will not exclude the operation of any principle of law or equity intended to protect and preserve the confidentiality of any confidential information that is the subject of this MoU.

5 Essential Patent Pool for AIDS Responsibilities

5.1 The EPPA will supply technical assistance and support to Country A for the implementation of this MoU.
5.2 The EPPA will supply legal and research assistance in the acquisition of both voluntary licenses and non-voluntary licenses to patents on essential medical technologies.
5.3 The EPPA will evaluate and recommend remuneration for use of essential patents for the treatment of AIDS.
5.4 The EPPA will establish a mechanism for the collection of royalties and the payment of royalties to patent owners.

6 Country A Responsibilities

6.1 Country A will remove all unnecessary regulatory and trade barriers that inhibit the implementation of this MoU and the end goal of facilitating the efficient manufacturing and distribution of essential treatments for AIDS to patients.
6.2 Country A will identify all patents in their country relevant to the treatment of AIDS.
6.3 Country A will collaborate with the EPPA to obtain voluntary licenses for essential patents for the treatment of AIDS.

6.4 When efforts to obtain voluntary licenses to essential patents for the treatment of AIDS are not successful within 90 days, Country A will collaborate with the EPPA to obtain non-voluntary authorizations to use such patents, in a manner consistent with the patent laws of Country A and any international trade agreement on patents that Country A is party to.

7 Cases involving voluntary authorizations

7.1 In the event that the voluntary negotiations for patent licenses are successful, and the EPPA obtains sufficient rights to use essential patents for countries not designated as high income by the World Bank, the EPPA will not pursue non-voluntary authorizations.

8 Terms for Terms for Non-Voluntary Licenses

8.1 For non-voluntary authorizations, Country A and the EPPA agree that essential patents for the treatment of AIDS should when possible be licensed on a non-exclusive non-discriminatory basis to any qualified importer, manufacturer or seller of essential medical treatments and devices for AIDS. Such licenses will be referred to as "open" licenses.

8.2 For non-voluntary authorizations, County A and the EPPA agree that Country A or the EPPA may impose conditions on qualified parties that ensure that users of the patents comply with necessary and beneficial obligations regarding transparency, solvency, payment of royalties and measures designed to ensure that products meet appropriate standards of quality.

9 Measures to ensure quality of products.

9.1 County A agrees to cooperate with the EPPA, other member countries who participate in the EPPA, the World Health Organization and donor organizations to support, develop and utilize mechanisims that enhance confidence in the qualify of essential medical treatments and devices for AIDS, including but not limited to such activities as the sharing of information regarding the quality of products offered by different manufacturers, importers and sellers, and reliance upon regulatory advice offered by such bodies as the WHO pre-qualification program or regulatory authorities in states with superior capacity to evaluate product quality.

10 Measures concerning cross-border trade in essential medical treatments and devices for AIDS.

10.1 Country A agrees to cooperate with the EPPA to facilitate the full use of the WTO August 30, 2003 decision to waive Article 31(f) of the TRIPS agreement in cases

where an importing country lacks sufficient capacity to manufacture to meet its needs.

10.2 Country A agrees to notify the World Trade Organization that it will use as an importer the system created by the August 30, 2003 decision by the WTO to waive Article 31(f) of the TRIPS.

10.3 [If not a least developed country] Country A agrees that for any product where it lacks the sufficient capacity to manufacture an essential treatment for AIDS efficiently, defined as the ability to manufacture a product within 20 percent of the cost of an imported product or at a price that is affordable to all, it will certify that it lacks sufficient capacity to manufacture the medical treatments and devices to meet its needs.

10.4 Country A and the EPPA agree to utilitize to the fullest additional mechanisms to authorize the efficent export and import of essential medical treatments and devices for AIDS, including but not limited to the export of essential medical treatments and devices in the following cases.

- i Exports of essential treatments and devices for AIDS from countries where patents are not in effect,
- ii Exports of essential treatments and devices for AIDS manufactured under voluntary licenses that authorize exports,
- iii Exports of essential treatments and devices for AIDS manufactured under compulsory licenses that permit exports of a non-predominant share of domestic production,
- iv Exports of essential treatments and devices for AIDS that are manufactured under non-voluntary authorizations that are a remedy to anticompetitive practices under Article 31(k) and/or Article 40 of the TRIPS agreement.
- v Exports of essential treatments and devices for AIDS that are authorized under Article 30 of the TRIPS agreement.
- vi Any other authorization for exports of essential treatments and devices for AIDS that are permitted under national laws and relevant international trade agreements.

11 Evaluation of Remuneration for Non-Voluntary Authorizations

11.1 Country A and EPPA agree that the EPPA evaluation of adequate remuneration for patent owners in cases involving non-voluntary authorizations to use patents will include but not be limited to evaluations of royalties using the following methods.

- i The royalty guidelines recommended in the 2001 Human Development Report by Published by UNDP.
- ii The royalty guidelines published by the Japanese Patent Office for the licensing of government owned inventions.
- iii The royalty guidelines issued by the Canadian government for the export of medicines under the August 30, 2003 WTO waiver of Article 31(f) of the TRIPS.
- iv The Equitable Royalty Method (see Attachment X).

11.2 The EPPA may also consider additional methods for determining adequate remuneration, including methodologies developed in consultation with Country A and other members of the EPPA, which are appropriate given the grounds for obtaining authorizations to use patents, including cases where authorizations are a remedy to anticompetitive practices.

11.3 The EPPA evaluation of adequate remuneration shall be consistent with objectives of paragraph 4 of the November 14, 2001 WTO Doha Declaration on TRIPS and Public Health Agreement, which states that patent laws "should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all."

11.4 Country A is not bound by EPPA recommendations for adequate remuneration.

12 Maintaining contact

12.1 The contact person for each party (see paragraph 13.6) will maintain appropriate lists of key staff and their contact details, and will, upon request in writing from the other party, provide details so that direct contact may be made.

12.2 The parties will assist each other when requested to identify sources of expertise to review applications or to review or provide other information.

12.3 Each party will include the other on mailing lists for relevant information, newsletters etc.

12.4 The parties will facilitate ongoing liaison by personal visits such as when personnel are in the area.

13 Administrative

13.1 The parties will facilitate ongoing liaison by personal visits such as when personnel are in the area.

13.2 The co-operative arrangements in this MoU will occur without costs or charges being levied between the parties.

13.3 Any variation to the provisions of this MoU may be proposed by either party to this MoU, but must mutually determined in writing by both parties to this MoU prior to the variation coming into effect.

13.4 The MoU will come into effect on the day on which it is signed.

13.5 Either Party may terminate this MoU by written notice to the other party. The MoU will terminate 90 calendar days after the date upon which the other party receives written notice of the intention to terminate. Any dispute over the terms of the MoU will be resolved by Arbitration under the International Commercial Arbitration and Conciliation rules of UNCITRAL.

13.6 The contact person for each party who is responsible for the administration of this MoU is:

_____	_____
_____	_____
_____	_____

Signed on this ___ ,day of _____ 2005.

(Signature)_____

(Name)_____

(Title)_____

Essential Patent Pool for AIDS

Signed on this ___ ,day of _____ 2005.

(Signature)_____

(Name)_____

(Title)_____

Country "A"