

ESSENTIAL INVENTIONS, INC
Po Box 19405, Washington, DC 20036 - Voice +1.202.387.8030, fax +1.202.234.5176
<http://www.essentialinventions.org>

January 17, 2005

WHO
UNAIDS
The Global Fund

Essential Inventions, Inc. proposes the creation of an Essential Patent Pool for AIDS (EPPA) as a tool to facilitate the sustainable scaling up on treatment for AIDS. The proposal draws from the US experience in creating the Manufacturers Aircraft Association (MAA) patent pool. The MAA was created in 1917 to overcome barriers for the scaling up of aircraft manufacturing, in response to a crisis -- the US decision to enter World War I. The creation of the EPPA is motivated by the crisis in access to essential treatments for AIDS.

A patent pool is an arrangement for the collective management of patent rights. Most patent pools today are based upon voluntary agreements, including for example patent pools involving the manufacture of DVDs, radios and other consumer electronic products, or patent pools on agriculture products or SARS. Patent pools can focus on upstream (R&D) or downstream (product) markets. There are also some patent pools which have been created with legislation, including as noted, the MAA aircraft patent pool, which was mandated with threats of compulsory licenses in 1917.

The rationale for creating a patent pool for essential treatments for AIDS is as follows:

- 1.1 The high cost of patented medical products, when marketed by a monopoly, is a barrier to providing access to medicines for all.
- 1.2 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.
- 1.3 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 efficient manufacturing of essential medical treatments and devices.
- 1.4 The multitude of patents, potential claims of infringement, variance of national laws, complexity of international treaties and national patent laws, and patent restrictions on the export of essential medical technologies, have presented barriers for access to medicines for all.

The EPPA would address these problems, and work as follows.

- 2.1 The patent pool would be created as a standalone non-profit entity.
- 2.2 The EPPA would identify essential patents for the treatment of AIDS in developing countries.
- 2.3 The EPPA would simultaneously negotiate agreements with patent holders and national governments.

- 2.4 Patent owners would be asked to voluntarily license patents to the EPPA, for use in countries not designed as high income by the World Bank.
- 2.5 In cases where the EPPA failed to obtain voluntary licenses, it would seek compulsory licenses.
- 2.6 Licensing by the EPPA, under voluntary or non-voluntary arrangements, would follow “best practice” models, including:
 - i. Consistency with national patent laws and trade agreements on patents,
 - ii. Non-discriminatory “open” license to any qualified party,
 - iii. Rights to manufacture, export, import and sell,
 - iv. Adequate remuneration using transparent and predictable royalty guidelines,
 - v. Requirements that patent owners met appropriate standards of quality.

The benefits of the EPPA to various parties can be summarized as follows:

- 3.1 Patients. The EPPA would promote competition and lower prices, particularly for newer regimes which do not currently have a significant generic market. The EPPA would also provide enhanced access to follow-on innovations, such as new FDCs, better heat stabilization, or other delivery mechanisms. Licenses would be tied to appropriate standards for product quality.
- 3.2 National governments. The EPPA would provide technical assistance, and a creditable and politically acceptable approach to the granting of compulsory licenses.
- 3.3 Patent owners. The EPPA would provide a predictable and fair system for remuneration, and would comply with national patent laws and trade agreements on patent rights.
- 3.4 Donors. The EPPA would ensure that the “solution” to the patent problem was focused on (a) the rule of law, (b) open competition, and (c) efficiency.

We wish to review with you several options to turn the EPPA into a reality, including:

- a. Directly fund the establishment of the EPPA.
- b. Endorse establishment of the EPPA
- c. Join a consortium of sponsors to establish the EPPA.

We look forward to reviewing the EPPA with your staff.

Sincerely,

Terry Gardiner
CEO
Essential Inventions, Inc.

Attachments:

Draft Memorandum of Understanding between the EPPA and Company A
Draft Memorandum of Understanding between the EPPA and Country A