

Essential Patent Pool for AIDS (EPPA)

Background Information

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by

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Patent Pools in Operation

The airplane patent pool is the most well known and parallel use of the patent pool to the proposed Essential Patent Pool for AIDS. The airplane patent pool was created by the United States Government in 1917 to meet a pressing need of the country. As the US contemplated the needs of entering and fighting in World War I, the problems associated with the development, manufacture, supply availability, innovation and cost of airplanes were brought to the forefront. A report issued by US Navy directed by Franklin Roosevelt found that,

“the development of the aircraft industry in the United States was seriously retarded by the existence of a chaotic situation concerning the validity and ownership of important aeronautical patents. This situation was one of great concern to the Government of the United States. . .”

Before the creation of the Airplane Patent Pool the innovation had been stifled and innovation was gridlocked by strangling patents. The cost of airplanes had been artificially pushed up by the limited patents controlled by a few companies. With the creation of the Patent Pool access to patent technology was licensed on a fair basis of remuneration to many companies. This allowed the creative talents of many companies to be unleashed. The supply and cost problems of airplanes was solved at the same time that innovation skyrocketed. The US Government not only solved its supply problem of new innovative airplanes it needed for World War I, but the modern US private sector aeronautical industry was born as private sector inventiveness was empowered.

Today patent pools are frequently utilized by the private sector companies in technology fields such as radio, DVD-video, DVD-ROM and MPEG_2 compression technology. The companies share royalties for the patents that are contributed voluntarily to the patent pools on a pre-determined basis. Innovation and rapid growth of industries has followed the creation of patent pools.

Another example of a budding patent pool is for a SARS vaccine. The WHO SARS Consultation Group and the key SARS IP owners, “SARS IP Working Group” are forging ahead to develop a patent pool. (Detail is available at the following WHO website) (<http://www.who.int/entity/intellectualproperty/events/en/JamesSimon.pdf>) This group has found that innovation will be delayed and constricted by the multiplicity and restriction of patents. Their review illustrates this problem by examination of the *Missing Cancer DNA Micro assay* whereby the development of a needed diagnostic for cancer was shelved due to the impossibility of assembling all the necessary patents to proceed with research and development.

A typical licensing requirement in these patent pools is a grantback licensing requirement whereby licensee’s grantback new patent rights to the pool participants. Patent holders have benefited by this rapid growth and innovation as well as consumers of the new products.

Essential Patent Pool for AIDS

Objectives

The objective of the Essential Patent Pool for AIDS (EPPA) is to enable a sustainable scale up of the global AIDS campaign and expansion of access and creation of needed technologies to combat the AIDS Pandemic. The goal is to provide Anti-retroviral (ARV) medicines, medical devices and testing regimes of acceptable quality and sustainable supply to countries and organizations working with the Global Fund, WHO, UNAIDS and other Partners.

Open Licensing

The EPPA would provide open licensing of patents in the pool to all suppliers of ARV medicines and other essential medical technologies for AIDS. This would have the result of lowering registration barriers and expanding the generic medicine markets.

Management of the Pool

The EPPA will be a independent non-profit entity established at the behest of sponsors such as the Africa Commission, Global Fund, WHO, UNAIDS or Donors. Once established the EPPA would independently operate as do other patent pools to fulfill its mission. The EPPA will be managed by its Board of Directors who would develop strategies and policies to transparently govern the organization. Board members will include representatives of National Governments and public health groups active in the global AIDS campaign. The Board of Directors will hire professional staff skilled in the administration of patent pools, modeled on the many successful private sector patent pool administrators.

Patents in the Pool

An initial list of patents needed in the pool will be developed by the EPPA by assessing the current needs of the Global Fund and its implementing partners. One of the ongoing function of all patent pools and hence the EPPA will be to assess the ongoing needs of additional patents and to respond to the application of other patent holders to join the patent pool.

After this patent list is developed the EPPA will seek voluntary contribution of patents by the patent holders to the EPPA for the manufacture, import and export of medical treatment components. The EPPA will sign Memorandums of Understanding with companies that hold essential patents specifying the terms and conditions that both the EPPA and the Company will operate by for these specific patents.

If voluntary negotiations fail within 90 days the Board of Directors will seek non-exclusive open compulsory licenses from appropriate WTO members. The EPPA will sign Memorandums of Understanding with National Governments that wish to participate in the pool. Countries that participate in the pool agree to issue licenses to any supplier to manufacture, import and/or export products, and to lower barriers to entry for firms.

New Patents

The history of patent pools has been that once they reach a certain threshold of establishment other patent holders will seek to join the patent pool. All patent pools must make an evaluation of whether patents are “essential” to meet legal and fairness criteria to all patent holders in the pool. For new patent holders seeking to join the EPPA an Expert Committee will evaluate whether patents are “essential patents” to the EPPA. Royalties will have to be re-distributed as new patents join the pool and product utilization under the license agreements changes.

Royalties

For products with markets in countries determined by the World Bank to be high income, remuneration for use of relevant patents will be determined by the “Equitable Royalty” method, and paid quarterly. The “Equitable Royalty” method is a system of determining equitable remuneration for products based upon the relative therapeutic benefits of products, and the affordability of royalties in countries depending upon average incomes and the extent of HIV/AIDS infection.

For a product with a market in a country designed as high income by the World Bank, the base royalty will be .04 multiplied by the median price of the product in the following seven high income countries: Canada, Germany, Italy, France, Spain, the United Kingdom and the United States.

The royalty for sales of a product in a country not designed as high income by the World Bank, which has an HIV/AIDS **infection rate no higher** than the average rate for countries designed as high income, will be calculated as follows. The base royalty, multiplied by the fraction that is the ratio of that country’s per capita GDP, divided by the average per capita GDP for all high-income countries. For example, for a product with high income price of \$8,000 annually, and a country with a per capita income that is .1 of the average per capita income for high income countries, the annual royalty would be $\$8,000 \times .04 \times .1 = \32 .

The royalty for sales of a product in a country not designed as high income by the World Bank, that has an HIV/AIDS **infection rate higher** than the average rate for countries designed as high income, will be calculated as follows. The base royalty, multiplied by the fraction that is the ratio of that country’s per GDP per person infected with HIV/AIDS, divided by the average GDP per person infected with HIV/AIDS, for all high-income countries.

For inventions not used in products with markets in countries determined by the World Bank to be high income, remuneration will be based upon the royalty guidelines published by the Japanese Patent Office for the licensing of government owned inventions.

For patents held by the patent pool royalties will be paid out to all patent holders on a pre-determined formula basis that takes into account the actual utilization of each patent in the manufacture of products by patent pool licensees. The EPPA will disperse quarterly royalty funds to companies for utilization of its patents by licensees of the patent pool.

Transparency and Fairness

For effective operation of the patent pool there will be full disclosure of royalty payments. There will be full disclosure of quantities of medicines supplied under the EPPA licenses by licensees. Licenses will be open to any supplier on non-discriminatory terms.

The EPPA License will require licensees to grant each of the licensing companies of EPPA a non-exclusive license on fair, reasonable and non-discriminatory terms to use any of their patents that are a product of licenses obtained from the EPPA.

Grantbacks and Innovation

Licensees of EPPA patents will agree to give back rights of any patents or technology built off the use of EPPA patents back to the Patent Pool. This will ensure that future medical technology and solutions for AIDS will be returned to the Patent Pool for future use and benefit of all licensees on the same terms and conditions that the EPPA licensed patents and licenses in the Pool originally.

Regulation of Quality

Licensees of EPPA patents will obtain relevant national regulatory approval or WHO pre-qualification to ensure necessary quality of medical products is maintained to guarantee quality health care to all patients globally.

Essential ARV for AIDS Patent Pool

*****Designated First Line by WHO*****

<u>Generic Name</u>	<u>Brand Name</u>	<u>Patentee</u>
Zidovudine	Retrovir (AZT)	Burroughs Wellcome
Lamivudine	Epivir (3TC)	IAF BioChem International, Inc.; Glaxo Wellcome; BioChem Pharma
Stavudine	Zerit (d4T)	Yale University
Efavirenz	Sustiva	Merck; DuPont; Bristol-Myers Squibb
Nevirapine	Viramune	Boehringer-Ingelheim

*****Newer Patents (Second Line)*****

<u>Generic Name</u>	<u>Brand Name</u>	<u>Patentee</u>
Delavirdine	Rescriptor	Upjohn; Pharmacia & Upjohn
Abacavir	Ziagen	Burroughs Wellcome; Glaxo Wellcome
Tenofovir	Viread	Ceskoslovenska akademik ved; Gilead ; Rega Stichting, v.z.w. (BE) Inst. of Organic Chemistry and Biochemistry of the Academy of (CZ);
Emtricitabine	Emtriva (FTC)	Emory University
Indinavir	Crixivan	Merck
Nelfinavir	Viracept	Agouron Pharmaceuticals
Ritonavir	Norvir	Abbott
Saquinavir	Invirase	Hoffman La-Roche
Amprenavir	Agenerase	Vertex Pharmaceuticals
Lopinavir/Rit.	Kaletra	Abbott
Atazanavir	Reyataz	Novartis; Bristol-Myers Squibb
Fosamprenavir	Lexiva	Vertex Pharmaceuticals; SmithKline Beecham
Fuzeon	Enfuvirtide	Duke University; Trimeris

Historical Patent Pools

<u>Name of Patent Pool</u>	<u>Year Established</u>
Sewing Machine	1856
Manufacturers Aircraft Association	1917
Radio Corporation of America	1924

Technology Patent Pools

<u>Name</u>	<u>No. of Members</u>	<u>No. of Patents</u>
MPEG 2	22 firms	Originally 27, now 640
DVD (3C)	3 firms	115 for manufacture of DVD Players 95 for the manufacture of discs
DVD (6C)	6 firms	All present and future patents
3G Platform	19 firms	All Essential patents of members
Via Licensing	3 Active Patent Pools	7 New Pools under Formation

Patent Pools Under Formation

<u>Name</u>	<u>Formation Group</u>
Agricultural Technology	PIPRA
Biotechnology	Cambia
SARS Vaccine	WHO SARS Working Group