

IGWG Submission on Collective Management of Intellectual Property -- The Use of Patent Pools to Expand Access to Needed Medical Technologies¹

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Introduction

The collective management of intellectual property rights, including the use of patent pools, can help the IGWG achieve its goals in the areas of promoting both new innovation and access to medicines.

The collective management of intellectual property rights is a name given to systems for aggregating and managing intellectual property rights, such as copyrights or patents. By pooling together assets, collective management systems can overcome market inefficiencies, offering lower transaction costs, and ensuring a more effective access to multiple rights. These systems facilitate the legitimate use of works and features to their users, by granting licenses and authorizations. Such arrangements can be made voluntarily or non-voluntarily, and involve a variety of different policy objectives, as well as legal and management regimes.

What is a patent pool?

Patent pools are one example of the collective management of intellectual property rights.²

A patent pool:

- is an agreement involving two or more patent owners to aggregate (pool) their patents and to license them to one another or to third parties, and
- usually offers standard licensing terms to licensees and allocate a portion of the licensing fees (royalties) to patent owners according to a pre-set formula or procedure.³

Pools are created for a variety of reasons by governments or the private sector, and can take many forms. A pool may involve simple cross-licensing among two or more competitors, in order to share a handful of patents necessary for the manufacture and sale of a particular product, or it may involve a large, industry-wide pool open to anyone, encompassing hundreds of manufacturers and thousands of patents, as well as other intellectual property, such as rights to use data, know-how or trademarks.

Patent Pools are not a new idea, and were widely used in the late 19th century for industries such as sewing machine manufacture. In recent years, patent pools have solved both R&D

¹ This note is based upon a KEI briefing note that includes contributions from Judit Rius, Michelle Childs, Spring Gombe, James Love, Jon Merz, Manon Ress and Terry Gardiner.

² Other examples include regimes of automatic compulsory licenses (statutory licenses), the voluntary or non-voluntary management of copyrights by collection societies, or alternative remuneration systems such as the proposed medical innovation prize fund.

³ Merges RP. "Institutions for intellectual property exchange: the case of patent pools." *Intellectual Products: Novel Claims to Protection and Their Boundaries*. Dreyfuss, R., ed. New York: Oxford Univ. Press, 2001. And Joel I. Klein. "[An Address to the American Intellectual Property Law Association](#), on the Subject of Cross-Licensing and Antitrust Law." May 2, 1997. (noting that *United States v. Line Materials*, 333 U.S. 287, 313 n.24 (1948) states that the term "patent pool" is not a term of art.)



(upstream) and access (downstream) problems within the manufacturing, metallurgical, paper, electrical, and chemical industries. Today, patent pools are frequently utilized in technology fields that require common standards, such as radio, DVD-video, DVD-ROM and MPEG_2 compression technology⁴. These patent pools have been instrumental in promoting investment in and utilization of new innovations.

There are precedents for government intervention to create a pool. In the U.S., for example, the Manufacturers Aircraft Association (MAA) pool was formed in 1917 against the backdrop of legislation threatening to compulsory license the patents, in order to overcome barriers for the scaling up of aircraft manufacturing, as the U.S. prepared to enter World War I.⁵ The U.S. government also insisted that rights to license patents for radio technologies be consolidated in order to promote the development of the modern radio industry.

Patent Pool Advantages

As the 1995 U.S. Department of Justice and the U.S. Federal Trade Commission Guidelines for licensing of intellectual property⁶ recognized, patent pools have several benefits including: a) clearing of blocking patents (patents that would be infringed when practicing another patents); b) reduction of licensing transaction costs through “one stop” licensing rather than multiple agreements; c) management of multiple owners and stacking of royalties, d) facilitation of professional management of the negotiation and administration of licensing arrangements; e) reduction of infringement litigation costs; f) the potential to encompass non patent technology and know-how; g) the potential to facilitate technology transfer and a sustainable scaling up of capacity and access in the developing world.⁷

Patent pools in medical technologies

The creation of patent pools to promote affordable access to medical technologies was proposed at the 14th Annual AIDS Conference in Barcelona⁸. Drawing from the U.S. experience in the Manufacturers Aircraft Association patent pool, which was created in response to a crisis: the U.S. decision to enter World War I. The proposal for the creation of a patent pool for access to medical technologies was motivated by the crisis in access to medical treatments in developing countries.

KEI has been working on several proposals to facilitate generic competition by providing much more efficient and effective mechanisms for the voluntary or compulsory licensing of patents. The rationale for creating a patent pool for medical technologies is as follows:

⁴ Serafino, D. “Survey of Patent Pools Demonstrates Variety of Purposes and Management Structures”. KEI Research Note, June 2007). Available at:

http://www.keionline.org/index.php?option=com_content&task=view&id=69

⁵ For more information, visit the CPTECH website on the Manufacturers Aircraft Association:

<http://www.cptech.org/cm/maa.html>. Also: Harry T. Dykman. “Patent Licensing within the Manufacturer’s Aircraft Association (MAA).” 46 J. PAT. OFF. SOC’Y 646, 648 (1964).

⁶ U.S. Department of Justice and Federal Trade Commission. “Antitrust Guidelines for the Licensing of Intellectual Property.” Washington D.C., April 6, 1995. Available online at:

<http://www.usdoj.gov/atr/public/guidelines/0558.htm>

⁷ Similar benefits were recognized by U.S. PTO. “Patent Pools: A Solution to the Problem of Access in Biotechnology Patents?” *USPTO*. December 5, 2000, pp. 8-10.

⁸ For a copy of the presentation, see: <http://www.cptech.org/slides/jameslove-barcelona.ppt>



- *Lower prices.* The high cost of patented medical and vaccines products, when marketed by a monopoly, is a barrier to providing access to medicines for all. Savings from using generic products can range from 50 to more than 95 percent.⁹
- *Innovation.* Patents on medical inventions may 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 are 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.
- *Enhanced capacity to manage legal issues.* The multitude of patents, potential claims of infringement, variance of national laws, complexity of international treaties and national patent laws, and complicated rules for the export of medical technologies under compulsory licenses present barriers for the expanded use of generic medicines. The patent pool would have the expertise and capacity to manage these issues on behalf of governments, donors, public health agencies, patent owners and generic manufacturers.
- *Economies of scale.* A patent pool that licenses patents in several countries can ensure that generic manufacturers operate at efficient economies of scale.
- *Global norm-setting.* Collective management will help to the establishment of global “best practices” norms for licensing on such issues as quality control, remuneration, open competition, etc.
- *Leadership.* By focusing attention on the pool, individual countries or government agencies would face less external pressures on issues relating to licensing of patents to generic manufacturers.

One example is found in the proposal to create an "upstream" pool to address R&D for a Severe Acute Respiratory Syndrome (SARS) vaccine. Following the outbreak of SARS, many research institutes and private firms rushed to sequence the SARS genome and apply for patents. The WHO SARS Consultation Group and key SARS intellectual property owners created the “SARS IP Working Group” which found that R&D would be delayed and constricted by the multiplicity of patents and that this may adversely affect the development of a vaccine. The group suggested that a patent pool should be instituted to promote the development of a treatment or vaccine.¹⁰

An example of a proposal that focuses on access to medicines is the June, 2006, Médecins Sans Frontières (MSF) and Essential Inventions proposal to UNITAID for the creation of a UNITAID

⁹ The prices for d4T (for a year supply) range from more than USD 4,000 for patented versions to less than USD 30 for generic versions. In 2007, the price for of the heart disease drug clopidogrel was 73 Baht per pill/day from Sanofi-Aventis, but less than 7 Baht from generic suppliers after a compulsory license was issued.

¹⁰ James H.M. Simon, et. al. “Managing severe acute respiratory syndrome (SARS) intellectual property rights: the possible role of patent pooling.” *WHO Bulletin*, vol. 83, no. 9. September 2005, 641-720. Available at: <http://www.who.int/bulletin/volumes/83/9/707.pdf>. And more information here: <http://www.who.int/entity/intellectualproperty/events/en/JamesSimon.pdf>



Medicines Patent Pool for patented medical technologies relevant to the treatment of HIV-AIDS. The proposal focus on patents required for:

- The development and production of generic fixed-dose combination TDF/3TC/EFV or NVP for adult use and for use in children.
- The development of generic versions of heat-stable lopinavir/ritonavir

The proposal currently under discussion at the UNITAID Board of Directors offers a mechanism for more efficient access to patented technologies, as well as licensing provisions to encourage follow-on innovation, and a system for royalties to be divided among patent owners on a pre-determined basis.

Separately from the UNITAID proposals, KEI and others have proposed the creation of the Essential Medical Invention Licensing Agency (EMILA), a non-profit entity to manage patent pools on behalf of donors, UN agencies, regional intergovernmental organizations or national governments. KEI has prepared a draft plan with proposed licenses patents and pharmaceutical test data.¹¹

Patent pools and the IGWG negotiation

The WHO's 2006 Report of the Commission on Intellectual Property Rights, Innovation and Public Health (CIPRH) goes into detail about the potential patent barriers to access affordable medical technologies and encouraged Pharmaceutical companies to grant voluntary licenses in developing countries and countries to fully use the TRIPS flexibilities to facilitate greater access to medicine.¹²

However, unless there is more clarity about how to overcome these patent barriers, prices will remain high, and it is unlikely that multiple generic medicine producers will enter the markets, so access targets will not be met. A patent pool could help establish such clarity and offer very practical ways to overcome the current patent barriers to access to medicines, enable a sustainable scale up of the production of medicines, expansion of access and creation of needed technologies developed for country-specific conditions.

The July 30, 2007 IGWG draft global strategy and plan of action on public health, innovation and intellectual property includes the promotion of patent pools in its recommendations for element 4 (transfer of technology) and indicates a time frame of 2008-2015.

During the IGWG negotiation at least the following countries has made statements in support of patent pool: France, WHO Eastern Mediterranean countries, India, Thailand, Netherland and Brazil. As an example, a French official told Intellectual Property Watch that France and rest of the intergovernmental medicine initiative UNITAID is “absolutely supporting” an idea to create a patent pooling mechanism. (IPW, 21 September 2006). He said the idea of pooling patents was more important for some diseases than others, especially certain HIV/AIDS medicines, and he believed this was an idea that could be supported in the working group as well. This is also

¹¹<http://www.keionline.org/misc-docs/emila.pdf>.

¹² Report of the Commission on Intellectual Property Rights, Innovation and Public Health (CIPRH). “Public Health: Innovation and Intellectual Property Rights.” Geneva: WHO, April 2006. Available online at: <http://www.who.int/intellectualproperty/en/>



identified as a bullet point in the WHO document. (source: <http://www.ipwatch.org/weblog/index.php?p=478>)

A pool can be a powerful tool to address several elements of the IGWG Strategy and Plan of Action:

- Promoting R&D, by limiting blocking patents and facilitating access to knowledge.
- Building innovative capacity, by easing the negotiations for access to IP.
- Transfer of technology, by lowering entry barriers for generic medicine manufacturers.
- Management of Intellectual property, by streamlining patenting and licensing arrangements.
- Improving delivery and access, by facilitating generic competition and low prices for products.

Practical Implementation: How a patent pool for medical technologies would work

The fundamental idea behind a patent pool for medical technologies is to facilitate competition by providing much more efficient and effective mechanisms for the voluntary or compulsory licensing of patents to generic suppliers.

There are a number of potential models for establishing a patent pool for access to medical technologies. One of the first is the proposal for a pool for essential medical technologies presented to WHO, UNAIDS and the Global Fund by Essential Inventions on 17th January, 2005¹³. Another is a patent pool for HIV-AIDS medical technologies that is currently being discussed by the UNITAID board. Another is the broader proposal for an Essential Medical Inventions Licensing Agency (EMILA) that includes a working plan and three model agreements¹⁴, a result of a broad consultation with industry and public health experts.

This is how it could work:

- The patent pool would be created. IGWG could explore whether existing organizations such as the WHO would be willing to host the Patent Pool or whether one or more new independent non-profit entities should be established.
- Some strategic decisions will need to be taken. The pool could be global or regional, for all medical technologies or for specific drug or vaccine. However, the area covered would have to be sufficiently large to ensure generic manufacturers could benefit from economies of scale.
- Professional staff skilled in the administration of patent pools would need to be hired, modeled on the many successful private sector patent pool administrators.

¹³ See: <http://www.essentialinventions.org/docs/eppa/>, and Proposal for Patent Pool for Essential Medicines (PPEM), Addis Ababa – 3rd March 2005

¹⁴ EMILA Working plan and model agreements are available at: <http://www.keionline.org/misc-docs/emila.pdf>



- The Pool would identify the patents necessary to achieve the objectives of the Pool.
- The Pool would simultaneously negotiate agreements with patent holders and national governments.
- The pool would execute Memoranda of Understanding (MOU) with governments, purchasing agencies and donors in order to generate support for the patent pool model as well as to facilitate cooperation between the numerous interested parties.
- Patent owners would be asked to voluntarily license patents to the Pool, for use in countries not designated as high income by the World Bank.
- In cases where the Pool failed to obtain voluntary licenses, it might ask governments under the terms of the MOU to seek compulsory licenses.
- Reasonable and standardized patent license terms should be drafted and signed with brand-name and generic pharmaceutical companies. Licenses would follow “best practice” models, including:
 - Consistency with national patent laws and trade agreements on patents,
 - Non-discriminatory, “open” licenses to any qualified party,
 - Rights to manufacture, export, import and sell,
 - Appropriate policies on a number of substantive issues, including remuneration, cross-licensing of improvements, conditions to ensure adequate product quality, distinctive packaging and labeling.
- If other intellectual property issues, such as rights to use or rely upon health registration data, were a problem for access to affordable medical technologies, the patent pool should also offer reasonable and standard terms.
- The Patent Pool would collect royalties from generic manufacturers and pay royalties to patent owners on a pre-determined transparent and predictable formula basis that takes into account the actual use of each patent in the manufacture of products by patent pool licensees. There are a number of royalty bases that could be used to balance the need for reasonable payment to rights holders with the necessity of increasing access by ensuring affordability.¹⁵ For example, the “Tiered Royalty Method” (TRM) is a system of determining equitable remuneration for products based upon their relative therapeutic benefits, and on the affordability of royalties in countries based upon average incomes and rates of infection.

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

- **Patients.** The Patent Pool would promote competition, lower prices, and enhance access to follow-on innovations, such as new Fixed Dose Combinations or delivery mechanisms. Licenses would be tied to appropriate standards for product quality.
- **National governments.** The Patent Pool would provide technical assistance, and a creditable and politically acceptable approach to the granting of compulsory licenses.
- **Patent owners.** The Patent Pool would provide a predictable and fair system for remuneration, respecting national patent laws and trade agreements on patent rights, and provide for cross-licensing of new patents that involve improvements on licensed products.
- **Donors.** The Patent Pool would ensure that the “solution” to the patent problem was focused on (a) the rule of law, (b) open competition, and (c) efficiency.

¹⁵ Love, James. “Remuneration guidelines for non-voluntary use of a patent on medical technologies.” *Health Economics and Drugs TCM Series No. 18.* WHO and UNDP, Geneva, 2005. Available at: http://www.who.int/medicines/areas/technical_cooperation/WHOTCM2005.1_OMS.pdf



The Patent Pools can be designed to assist the efficient management of intellectual property rights in order to provide affordable access to medical technologies, while facilitating innovation by competitors. A pool can enhance transparency, promote good practices for quality of products, and follow global and national legal rules on the protection of intellectual property.

MORE INFORMATION

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