



Proposals for New and Innovative Sources of Funding Medicines Patent Pool

Introduction

The Secretariat on Public Health, Innovation and Intellectual Property (PHI) was established by WHO to facilitate the follow-up to the report of the Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH). Resolution WHA59.24 requested the Director-General to convene an Intergovernmental Working Group (IGWG) to draw up a global strategy and plan of action aimed at, inter alia, securing an enhanced and sustainable basis for needs-driven, essential health research and development relevant to diseases that disproportionately affect developing countries. The IGWG resulted in the adoption by the sixty-first World Health Assembly of the *Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property* in May 2008.¹ The results of the IGWG create the opportunity to develop alternative financing mechanisms for R&D, i.e., “to examine current financing and coordination of research and development, as well as proposals for new and innovative sources of funding”.

UNITAID provides the present submission to explain how the UNITAID patent pool contributes to this aspect of the *Global Strategy and Plan of Action* and offers new mechanisms to develop adapted formulations of AIDS medication for use by children and adults as well as can help accelerate the availability of affordable treatments. UNITAID is a new financing mechanism, based on the concept of a solidarity tax on airline tickets, established to provide long-term, sustainable and predictable funding to increase access to and reduce prices of quality drugs and diagnostics for the treatment of HIV/AIDS, malaria and tuberculosis in developing countries. On average UNITAID has spent 300 million USD per year on the purchase of medical goods for HIV/AIDS, TB and malaria.

1. At the outset, UNITAID notes that the new WHO Global Strategy And Plan Of Action On Public Health, Innovation And Intellectual Property (WHA 61.21) calls for the creation of new patent pools for both upstream and downstream uses.

2. UNITAID notes that, in July of 2008, the UNITAID executive board decided to take the necessary steps to set up a medicines patent pool. The initial focus of the UNITAID development of the patent pool will be on medicines for HIV/AIDS. The aim of the initiative is to improve access to patents and other relevant intellectual property (IP) to boost the availability of more affordable versions of antiretroviral medicines (ARVs) and to encourage the development and availability of better adapted formulations such as once daily, heat stable, fixed dose formulations and paediatric formulations of essential ARVs.

¹ http://www.who.int/gb/ebwha/pdf_files/A61/A61_R21-en.pdf

3. UNITAID believes, however, that as a voluntary mechanism, a patent pool should include patents relating to fixed-dose combinations of ARVs for adult and paediatric use, provide the opportunity for the patent owners to voluntarily license patents needed for the production and dissemination of ARVs to address low and middle income country needs. If proven effective a patent pool model may be expandable to patents for other diseases of high prevalence in low and middle income countries.

4. UNITAID further notes that governments of Barbados and Bolivia have asked the WHO Expert Group on R&D Financing to consider combining a voluntary patent pool model with an incentive for the patent owners in the form of a prize fund. That is, the intention is to create a prize fund from Global Fund, PEPFAR or UNITAID budgets to reward entities that license patents to the patent pool. This idea of potentially linking a voluntary patent pool and a prize incentive mechanism may be a new business model for drug development, one that breaks the link between drug prices and R&D incentives. UNITAID will follow the development of these proposals closely.

What is a Patent Pool?

5. A patent pool is a portfolio of assets consisting of the entire set of patents (and, if desired, know-how, dossiers submitted to a regulatory agency and other intellectual assets) held by various actors (companies, universities, government institutions) related to a particular technology. This intellectual property is made available on a non-exclusive basis to a group of manufacturers and distributors of medicines. Most contemporary pools have been established by industry to facilitate the development of information technology (IT) products based on a series of IT standards defined by one or more standard-setting organizations .

6. In one possible model, the pool is operated under the auspices of a licensing agency which holds licenses to the patents (and other intellectual assets) for sub-license to manufacturers and distributors. The licensing agency collects royalties and distributes them to the patent (and other intellectual asset) holders. The licensing agency can, in principle, manage a variety of pools. While UNITAID would be involved in the design and strategic implementation of the pool, the licensing authority would be legally separate from it.

7. Assuring the quality of the medicines that are developed as a result of the pool will be an important emphasis for UNITAID and will require close collaboration with the WHO Prequalification Project.

8. A number of newer collective IP management schemes have been proposed to address the needs of a diverse set of patent users. Examples of this latter approach are the proposed SARS patent pool, developed by public institutions to facilitate the development of a needed vaccine, the collective management scheme for the important research tool Green Fluorescent Protein, the Golden Rice Patent Pool, and the Open Invention Network (OIN) for Linux Software.

Both “upstream” and “downstream” patent pools are possible and the reasons for creating these collective IP management schemes are summarized below.

“Upstream” Patent Pool for Fixed Dose Combination (FDC) antiretrovirals

9. The reason for creating an “upstream” patent pool can be summarized as follows: Adult and paediatric FDCs are needed to anticipate increasing resistance to existing ARVs and/or because FDCs will have other clinical benefits (e.g., improved adherence; improved heat stability, easier record keeping and supply chain management). Nonetheless, new adult and paediatric FDCs are not presently available because more R&D work is needed to develop them. Unfortunately, more R&D work on these new adult and paediatric FDCs is not forthcoming because IP access by potential developers is limited due to multiple, blocking ownership of individual FDC components. Moreover, development and availability of better adapted FDCs formulations is needed but is inhibited by high transaction costs due to multiple ownerships. Technological standards for new FDCs are presently not widely disseminated but such standards are a foundation upon which to develop and sell certain products in the market.

“Downstream” Patent Pool for Fixed Dose Combination (FDC) antiretrovirals

10. The reason for creating a “downstream” patent pool can be summarized as follows: Effective adult and paediatric FDCs exist to fill a clinical need but they require lower prices to increase access in certain markets and maintain the sustainability of long-term ARV treatments. Nonetheless, public health benefits do not presently accrue to all countries as access to more appropriate and affordable medicines is still limited in many countries. Unfortunately, the IP landscape has significantly changed over time as more and more ARVs are being patented in more and more countries- in contrast to the situation in the late 1990s. Marketing is inhibited and prices are high because of limited IP access since multiple ownership of individual FDC components increases license transaction / administration / litigation costs and because multiple licenses need to be negotiated for production. Thus, this “IP access barrier” inhibits downstream technology transfer / production efficiencies / economies of scale and discourages multiple manufacturers from competing against each other on price of medicines.

11. In collaboration with both the WHO HIV/AIDS programme well as the Essential Medicines and Pharmaceutical Policies department, a list of priority ARV products was developed and submitted for discussion at the 17th WHO Expert Committee on Essential Medicines, held from 23 to 27 March 2009. The WHO/UNITAID background document for discussion at the 17th WHO Expert Committee on Essential Medicines is available at: http://www.who.int/selection_medicines/committees/expert/17/Essential_Missing_ARVS.pdf

Potential Benefits of a Patent Pool

12. *Global Benefits* include the following

- Health benefits to developing countries through access to more appropriate and affordable medicines,
- The development of more appropriate formulations for existing medicines as well as that of new medicines (FDCs and novel formulations),
- The development of licensing expertise in low and middle income countries to facilitate future introductions of medicines through an established network,

- Increasing competition in the supply of medicines,
- Increasing sources of essential medicines which leads to lower prices and improved ability to react to stock outs,
- Technology transfer to developing country producers,
- Through UNITAID's relationship with the licensing agency, a better understanding of the need of those producing and distributing medicines,
- A privileged network through which to purchase quality medicines,
- The sharing of improvements and know-how among manufacturers to increase quality and the availability of new products.

13. *Benefits to patent (and other intellectual asset) holders*

- Improved public standing by actively supporting access to medicines,
- Handing over responsibility for the manufacture and distribution of medicines covered by the pool to the licensees and reduction of transaction costs,
- Revenues through the creation of new markets,
- Access to improvements and know-how relating to the medicines within the pool,
- A better understanding of the needs and environment in low and middle income countries,
- Easy procedures for licensing,
- Based on voluntary licensing principles,
- Receipt of royalty payments.

14. *Benefits to licensee manufacturers*

- Access to patented technology under reasonable terms and reasonable payment of royalties,
- No need for license negotiations with multiple patent holders,
- The ability to compete in new product areas,
- Access to improvements and know-how,
- Development of research and development capacity,
- Revenues from products.

15. *Benefits to patients (and/or their countries)*

- Increased sources of medicines at affordable prices,
- Access to new classes of ARVs at an early stage (and well before patent term expiration),
- Availability of adapted fixed dose combinations for adults,
- Accelerate the development of adapted formulations for the treatment of children,
- New medicines suited to their needs and environments,
- Faster introduction of new medicines in low income markets,
- An increased rate of innovation,
- Lower prices.

The UNITAID Secretariat is consulting with various stakeholders, seeking input for the development of a full implementation plan for the HIV medicines patent pool which is scheduled for consideration by the UNITAID Executive Board in November 2009.

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