Recommendations to the UNITAID Patent Pool Initiative:

A “Square” Model

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POLICY DESCRIPTION

Generally, in HIV/AIDS treatment, as medicine patent system protects the rights and the interests of patent holders, in some way it sets limitations for the general access to AIDS treatment globally. First, the original price of patented drugs is expensive. People in need of taking antiretroviral therapy in many developing countries usually have limited scope of selections on drug combinations, especially for the patients who have resisted to the first-line medicines. Second, to meet more patients’ need, many developing countries produce generic version of old drugs that have not been protected by the patent system. Compared with new drugs, the old treatment regimen has more side effects. Additionally, being held in different pharmaceutical companies, it also set some obstacles on developing fixed-dose combinations (FDC) and child-friendly medicines that “combine several medicines into one pill (UNITAID, 2010b)”. To make the global AIDS treatments more accessible, UNITAID launched the first patent pool for AIDS medicines in July 2010, aiming at “pooling” AIDS medicines held by different pharmaceutical companies and organizations to lower the price of critical ARV drugs.

Established in September 2006 (UNITAID, 2010b), UNITAID is an international health financing organization cofounded by UK, Chile, Brazil, Norway and France and funded by a levy on airline tickets. As an innovative financing mechanism, UNITAID uses market-based tools to expand access to quality life-saving treatment for HIV/AIDS, TB and Malaria (UNITAID, 2010b). Its goal is using innovative, global market-based approaches to improve public health by increasing access to quality products to treat, diagnose and prevent HIV/AIDS, tuberculosis, malaria and related co-morbidities in developing countries (UNITAID, 2009).
The HIV patent pool, launched by UNITAID, is intended to (1) seek licenses for newer ARV medicines with a high price manufactured in developing countries, such as improved first-line ARV regimens or second- and third-line regimens; (2) seek licenses for technology that could be used to develop important products that are currently unavailable, such as medicines adapted from children (UNITAID, 2010a).

**STRENGTHS OF THE PATENT POOL**

Compared with TRIPS Compulsory Licensing and time-limited donation programs, the HIV patent pool is a groundbreaking strategy in addressing the accessibility of AIDS treatment within the international AIDS community. First, through donating drug licenses, the generic versions can be manufactured by most developing countries at an affordable price, directly contributing to the globally general Antiretroviral Therapy (ARV) accessibility. Second, pooling the major patents can be a more sustainable method for authorized generic drug to be produced. Finally, the development of FDCs can become much more cost-efficient by sharing the patents among volunteer pharmaceutical companies in the pool.

**CHALLENGES FACING THE CURRENT PATENT POOL**

Currently, the major challenge facing the patent pool is that numerous major pharmaceutical companies expressed their hesitations on joining the patent pool. There are multiple factors contributing to the current situation. First, for pharmaceutical companies, donating patents would lead to a great profit loss due to the authorization of generic drug production. Second, although collaborative partnerships between the companies exist, the competitive relationships dominate the pharmaceutical market. However, the rationale of the HIV patent pool is largely grounded on the collaborations
among different patent holders. Given this structural contradiction which is difficult to be challenged, pooling patents may not be realized if there are not powerful incentives for patent donators. One of the potential incentives is the patent sharing among volunteer pharmaceutical companies, which allows them to develop FDCs and broaden research area in a cost-efficient manner. However, this incentive is based on pharmaceutical companies’ wide participation and donation. Finally, although several companies have signed their voluntary license agreements with generic manufacturers, “most agreements so far are overly restrictive in terms of which regions they cover, and leave out too many people living with HIV and do not include enough generic companies to create the level of competition needed to sufficiently drive prices down” (Campaign For Access To Essential Medicines (CFATEM), 2011).

COMMUNITY PARTICIPATION AND PODS ISSUES

First, although numerous AIDS-related donations come into developing countries, there are still many discrepancies in accessing ARV drugs between the poor countries and the rich ones. The intellectual property protection system unintentionally contributes to generating a geographic privilege of accessing the ARV drugs. In the countries where the major ARV drug manufacturers are based, AIDS can be seen as a chronic disease because effective treatment can be sustained. However, HIV/AIDS still largely shorten people’s life expectation in South Africa. Second, sometimes one form of discrepancy may make another group of people/community become oppressed due to less accessing resources and/or lacking decision-making power. In the global AIDS community in need of AIDS treatment, a series of symptoms of AIDS and related discriminations weaken the patients intellectually and physically, making them become more voiceless, powerless
and oppressed. Basically, by authorizing the generic drugs’ production, the patent pool can contribute to reducing the discrepancies between the privileged and the oppressed. Besides, the development of FDCs and child-friendly medicines facilitated by the AIDS patent pool demonstrates the understanding and respect to the diversity of medicine users to a large extent.

Given the access to AIDS medicines, the human Survival right of the patients in developing countries are protected, which is one of the important foundations of the fulfillment of social justice from the perspective of outcome justice. However, the social justice is not merely limited to the outcome justice. Craig defines social justice as “maximizing the reduction of inequalities in wealth, income and life chances; and the participation of all, including the most disadvantaged. (Michael O'Brien, 2011)” The participation of the most disadvantaged should be involved in the process of attaining social justice. Although people of AIDS community eventually are the critical and direct beneficiaries, in both the launching period and implementation period of the AIDS patent pool, the participation of people living with HIV/AIDS is very difficult to identify. In this perspective, the procedural justice is not reflected in current patent pool.

RECOMMENDATIONS

Rationale: Grounded on the major goals, general accessibility of AIDS medicines and medicine innovation, the AIDS patent pool is advocating for a broad collaboration of major pharmaceutical companies. Simultaneously, the non-profit nature of UNITAID determinates that each patent holder joining the pool (e.g. pharmaceutical companies or governmental HIV/AIDS medicine development organizations) have to face profit
reduction. Taking into consideration the profit nature of pharmaceutical companies, it is understandable that most pharmaceutical manufacturers expressed their hesitations in joining the pool and in collaboration with other companies. The first patent donator joining the pool is National Institutes of Health (NIH), which is operated by the US government. The contradictive natures between UNITAID and patent holders also make their partnership unstable. Therefore, an alternative for promoting the collaborative relationship is to introduce multiple stakeholders concerning the AIDS medicine patent issues into the establishment and structure of the patent pool.

**Shifting “Line” collaborative model to “Square” collaborative model**

The diagram 1 presents the current situation of the AIDS patent pool, which can be seen as a “line” collaborative model. As a non-profit organization, UNITAID provides operation funds, human power and management for the patent pool, which is strongly supportive to the existence and maintenance of the pool. Ideally, the relationship between
the patent holders and the patent pool would be mutually beneficial to each other. The patent holders put drug patents into the pool in exchange of getting cost-efficient access to other drug patents. However, due to the lack of patent donators in the pool, the major patent holders feel hesitated to join because they have to undertake the profit loss rather than benefiting from the “pooled patents”. The current strategy used by UNITAID is negotiating with each major pharmaceutical company holding critical ARV drug patents. So far, UNITAID has negotiated with several big pharmaceutical companies, and F. Hoffman-La Roche, Gilead Sciences, Sequoia Pharmaceuticals, and ViiV Healthcare (a joint venture of GlaxoSmithKline and Pfizer) have entered or have shown their willingness of entering into negotiations (the Guardian, 2011). The others are still hesitant to expressing their intentions. Since not addressing the contradictive natures of two parties (profit-driven vs. volunteerism), it is less effective to do so.

To assist the AIDS patent pool better and effective functioning in fulfilling its missions, an alternative is to introduce two other stakeholders into the pool – the US government and the global AIDS community – into the supporting structure of the patent pool.
The diagram 2 illustrates a “Square” Collaborative Model of operating the patent pool. The collaboration of the US government and a broader participation of the global AIDS community can be supportive forces to motivate the donating behaviors of medicine patent holders. The “Square” collaborative model provides a more sustainable and stable support to fulfill the mission of the AIDS patent pool.

**Revised goals:** The two major goals of the ‘Line’ model of the patent pool are AIDS treatment accessibility and the cost-efficient way of development of FDCs. Based on the importance of both procedural and outcome justice, the new “Square” model involves two other goals: (1) ensuring increased participation of global AIDS community in policy implementation; and (2) motivating the participation of the federal government in order to facilitate an more efficient operation of the patent pool. The global AIDS community includes AIDS patients who have access to treatment, patients in need of treatment and AIDS activists and policy practitioners.

**Details:** The patent pool requires a transition period, which is the period that the voluntary pharmaceutical companies are in the process of decision-making and/or clarifying detailed information. During the transition period, an inevitable phenomenon is that several patent holders have been in the patent pool while others are not. In another word, the patent holders already in the pool may not largely benefit from the patent sharing incentive, which makes profit loss. Therefore, the U.S. government may take a positive role in reducing their concerns on it.

The U.S. government has made its commitment and launched several programs and plans to improve both the global health and the universal access to ARV drugs, such as the Obama administrations’ six-year Global Health Initiative and U.S. President’s
Emergency Plan for AIDS Relief (PEPFAR). Therefore, part of the funds can be used into facilitating the patent pool making the aid plan more sustainable and effective. One strategy that the government may take into consideration is launching an incentive of tax break to the pharmaceutical companies for joining in the pool during the transition period. More specifically, once a pharmaceutical company decides to donate one or more than one AIDS medicine patents, its tax can be reduced by certain “Units”. The amount of Units that one pharmaceutical company can be given is determined by the number of patents that it donates.

The exact percentage value of one Unit should be calculated and assessed by the government and UNITAID. The major indicators of defining the “Unit value” includes (1) the funding of global AIDS health budget of the United States; (2) patent holders’ average profit loss of donating one patent; and (3) the extended medicine market in developing countries that pharmaceutical companies may have. One possible outcome is that the tax break incentive for patent holders can merely offset partial profit loss. If that is the case, the government and UNITAID should clarify it to the donators and negotiate with them to take their responsibilities to the global AIDS community. Additionally, the tax break incentive can be replaced by research funding or other forms of financial compensations.

To better urge the pharmaceutical companies to take action and take their social responsibilities to the global AIDS community, the AIDS community per se should advocate for themselves. International community practitioners and AIDS activists can become important roles in strengthening the community participation. Although there are numerous people living with HIV/AIDS who have been empowered to become AIDS
activists advocating a series of critical issues for the AIDS community as a whole, the most of the community are in silence. The empowered AIDS activists, community social workers and policy practitioners should help unite the global AIDS community as a stronger power and train more community members to be aware of their basic human surviving rights. The people of the community who have sustained AIDS treatments can play an important role in doing community right advocacy by using various advocacy tools (e.g. demonstration, and advocacy op-ed articles, etc.). A series of trainings should be provided by well-educated community members and social workers. The community participation in conducting evidence-based advocacy work and expressing their needs can to a large extent activate more influential people and/or entities (governments of developed countries and pharmaceutical companies) to understand the current situation and take actions to make changes in order to benefit the oppressed and human beings in a life-threatening situation. As the most critical beneficiaries, in some way the global AIDS community is supposed to be a sustained group in doing human right advocacy work for themselves.

**CRITERION ALTERNATIVE MATRIX: “Line” Model vs. “Square” Model**

**Explanation of indicators:** To make the criterion just, grounded on the best interests of the global AIDS community, six indicators (shown in the table 1) are selected to conduct the alternatives evaluation. General AIDS treatment accessibility, waiting time for benefiting the community and the sustainability of the patent pool are directly associated with the basic survival rights of people in need of AIDS treatments and their life quality. The incentive and FDCs development are directly influence the intention of pharmaceutical companies in joining the pool and eventually benefit the global AIDS
community. Rated on a 5-point scale (1= Poor, 2= Fair, 3= Moderate, 4= Good, 5= excellent), each of the criteria is weighted equally.

**CAM:** The CAM is used to make a comparison of the current “Line” collaborative model and the alternative “Square” collaborative model on the following indicators.

**Table 1.**

<table>
<thead>
<tr>
<th>Alternatives</th>
<th>“Line” Model</th>
<th>“Square” Model</th>
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<tbody>
<tr>
<td>General AIDS treatment accessibility</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td>Community rights awareness and participation</td>
<td>2</td>
<td>5</td>
</tr>
<tr>
<td>The sustainability of the patent pool</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Waiting time for benefiting the community</td>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td>Incentives for pharmaceutical companies</td>
<td>3</td>
<td>5</td>
</tr>
<tr>
<td>FDCs development</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td>Social justice</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td><strong>Total score</strong></td>
<td><strong>24</strong></td>
<td><strong>33</strong></td>
</tr>
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</table>

Note: 1= Poor, 2= Fair, 3= Moderate, 4= Good, 5= excellent

Overall, the score of the “Square” model is much higher than the “Line” model. More specifically, both the “Line” model and the “Square” model are scored the highest level – 5 – on general AIDS treatment accessibility, because this indicator is the major purpose of both models. Once the pool involves sufficient patent holders, the general AIDS drugs accessibility (at least the major critical drugs) would be achieved in a sustainable manner. Based on the “patent-sharing” principle, the development of FDCs can be accelerated in a more cost-efficient way for both models. Therefore, 5 score is given for each model.
Based on the analysis of “Line” model, its disagreement with the profit pharmaceutical companies by nature and lacking of community participation make its sustainability less than the “Square” model. For the “Square” model, the advocacy work of community participation and the support of federal government can facilitate the pool’s sustainability to a large extent, but the competition relationship among different companies in pharmaceutical market still exists and cannot be eliminated. Therefore, the “Line” model is scored 3 whereas the “Square” model is 4.

Obviously, the community participation is involved and strengthened in the “Square” model, which is a major improvement for the patent pool. This improvement not only strengthens the community’s capacity of self-advocating but facilitates the better understanding to the community’s needs and potential power. The CAM scores the “Line” model 2 as a result of lacking community participation whereas gives 5 for the “Square” model.

In the “Square” model, two other major improvements are “waiting time for benefiting the community” and “incentives for the pharmaceutical companies”. The current situation of the patent pool demonstrates a slow development due to multiple reasons. However, the “Square” model strengthens the structural change within the pool, which accelerates the fulfillment of its goals. Simultaneously, the “Square” model contains dual incentives (tax break given by the government and patent-sharing principle), which is the reason of being given 5 scores.

Finally, because of lacking the process of community participation, the “Line” model (4) was scored less than the “Square” model (5), though both of the models reflect its critical foundation of improving social justice among global AIDS community.
In summary, the “Square” collective model of facilitating the patent pool’s function is grounded on combining the four powers – UNITAID, Patent Holders, the US government and the global AIDS community - to support the operation of the AIDS patent pool in an effective manner.

**POLICY EVALUATION**

The process of evaluating policy is to deeply understand to what extent the goals of the policy are achieved. Additionally, in the process of policy implementation, how is the social justice reflected. The evaluation of the AIDS patent pool includes procedural evaluation and outcome evaluation. Based on the goals of the revised model, table 2 presents the details of the evaluation indicators of the “Square” model.

<table>
<thead>
<tr>
<th></th>
<th>Procedural evaluation</th>
<th>Outcome evaluation</th>
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| Patent holders       | To what extent the patent holders participate in the principle making and needs assessment; their motivation in joining patent pool; their collaborations with other patent donators | Quantity and quality of FDCs development  
|                      |                                                                                      | Quantity of donated drug patents                                                  |
| Government           | To what extent the AIDS community and patent holders participate in the decision making process of government (e.g. is the amount of governmental funding based on the consideration of both the community needs and patent holders’ interests?) | Financial input and output analysis (evaluate the efficiency of funding the patent pool; comparison with funding other global AIDS treatment program, etc.) |
| AIDS community       | To what extent the community can express their needs and suggestions?  
|                      | How many methods are used in helping the community to express                          | AIDS treatment coverage and side effects of the treatment  
|                      |                                                                                      | Death rate  
<p>|                      |                                                                                      | Child AIDS treatment accessibility                                                  |</p>
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<th>themselves?</th>
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<tr>
<td>UNITAID</td>
<td>The monitoring process of the use of funding (transparency and efficacy); decision mechanism and democratic decision making</td>
</tr>
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In order to conduct the policy evaluation, many evaluation tools can be utilized. For example, the UNITAID can organize evaluation meeting inviting patent donators, AIDS community members and government officers. One-on-one interview also can be conducted among patent holders. To evaluate the community participation, a focus group is an alternative. Additionally, to access the data of treatment coverage, the UNITAID can collaborate with both official AIDS data collection agency (e.g. WTO or UNAIDS) and pharmaceutical companies (e.g. their sales amount).

REFERENCES


