

# WORKING DOCUMENT - BARBADOS AND BOLIVIA

## PROPOSAL 5

### A Licensed Products Prize Fund (LP/pf) for Donors

#### A Solution for Donor-Supported Markets: Rewards Linked to Competitive Supply of Products for HIV-AIDS, TB, Malaria and Other Humanitarian Uses

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### The Problem

In the area of HIV-AIDS, TB and malaria, initiatives such as the Global Fund, UNITAID and the US government-funded PEPFAR program provide global donor support for access to lifesaving medicines. That donor support is predicated on the expectation that treatment costs will be low (and that medicines will be available at low prices).

Some drug developers seek very aggressive high prices on newer medicines, while other drug developers voluntarily abandon monopolies in developing country markets. The rise of donor funding for essential medicines has also encouraged greater patenting of products in developing countries for some products. For example, patents were reportedly sought in 38 African countries, including several least developed countries (LDCs), for the HIV-AIDS drug FTC, which was developed with US government support. An earlier product developed by the same company, before the creation of the Global Fund, was patented in zero African countries.

HIV-AIDS treatment regimes in developing country markets are distorted by the highly arbitrary nature of prices for second and third generation medicines. Such high prices put at risk the sustainability of the funding, as donors may choose to look elsewhere where humanitarian projects are more cost-effective in terms of benefits per dollar spent.

The challenge is to ensure that the humanitarian programs are as cost-effective as possible, while preserving appropriate rewards for product developers.

## **The Simple Reward System for the Global Fund, PEPFAR and UNITAID**

### ***The Donor Patent Pool***

The major projects providing humanitarian aid in the areas of HIV-AIDS, TB and malaria should agree upon norms for the non-exclusive voluntary licensing of product and process patents, rights in data and know-how. A pool to manage these rights will be created. Such a pool should address appropriate concerns of right-owners regarding acceptable standards for product quality, transparency, adequate remuneration, management of intellectual property rights relating to improvements or other follow-on inventions involving licensed products, and other relevant issues. The pool should offer out-licenses to generic suppliers on a non-discriminatory basis, for use in countries that are not high-income (The Donor Patent Pool, or Donor/pp).

### ***Licensed Product Prizes***

The donors should set aside a fraction of their drug purchase budgets to reward developers who license innovations to the patent pool. One suggestion is 10 percent of all drug purchases. This money would be placed in a Licensed Products Prize Fund (LP/pf).

Participation in the Licensed Product Prize Fund (LP/pf) would be strictly voluntary. Because the rewards would only be available to products that were licensed to the Donor/pp, the incentives to license to the pool would be strong, particularly for the early entrants. Consider the following:

1. Each product is likely to have limited patent coverage in the developing world.
2. Even where patents are obtained in developing countries, the patent-owner is subject to compulsory licenses, or the threat of compulsory licenses, to negotiate lower prices.
3. Developers of products cannot control large segments of the market where they face generic competition.
4. The LP/pf would only give rewards to developers of products. Generic manufactures of inexpensive versions of the products would only benefit from the LP/pf if they provide new innovations such as improved process or delivery methods, all of which would be subject to grant-back provisions benefiting the original product developer, if both parties were participating in the Donor/pp.
5. If only a small number of firms license to the Donor/pp, they would reap enormous returns from the LP/pf. As more firms license products to the Donor/pp, the rewards available to each developer would fall.

The prize awards will be divided among competitors on the basis of the relative impact of the products on health outcomes. It would not matter who actually manufactured and distributed the products. Utilization of generic copies of EFV/3TC/TDF or LPV/r would generate claims against the LP/pf for the original product developers.

The LP/pf would make payments to developers regardless of the status of the patents, so long as the developers license whatever rights exist to the Donor/pp. This would reduce the incentive now seen to patent products in developing countries, and ensure that new, open-source development models would be rewarded to the degree that they succeed in improving health outcomes.

One issue to be resolved would be the cases where the product developer wanted to license patent rights in some countries, but not others. One approach would be to only make the LP/pf rewards available to developers that licensed in all countries. Another would be to introduce significant reductions in the rewards for a partial rather than a full license.

### **Benefits of the New Business Model**

If product developers accepted the Donor/pp and LP/pf combination, it would offer many benefits. Drug developers would negotiate with donors over the share of the drug budget to be allocated as rewards, but would also signal an acceptance of competition and marginal cost pricing of the products themselves, in areas where the market is primarily supported by humanitarian donors. This actually makes the supply of donor resources more attractive and sustainable in the longer run.

The rewards to drug developers would also be rationally related to the benefits of products in resource-poor, developing country markets, giving drug developers more incentive to collaborate or invest in better delivery systems for those products in developing countries.

### **WHO meeting on this proposal**

The WHO should hold a meeting in March of 2009 to consider this proposal. Donors, Member States and interested stakeholders should be invited to participate.