

PROPOSAL by Barbados, Bolivia, Suriname and Bangladesh

A Prize Fund to Support Innovation and Access for Donor Supported Markets

Linking Rewards for Innovation to the Competitive Supply of Products for HIV-AIDS, TB, Malaria and Other Diseases for Humanitarian Uses

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Executive Summary

The governments of Bangladesh, Barbados, Bolivia and Suriname present for discussion a proposal for the possible use of new incentive mechanisms for innovation that separate rewards to innovation from the price of medicines, vaccines, diagnostic kits and other health-care products.

The proposal presents a possible solution for reconciling innovation and access for certain markets where donors play an important role on the demand side.

An R&D reward system is presented, and linked to voluntary agreements to license the competitive supply of products for HIV-AIDS, TB and malaria and other diseases for humanitarian uses. This proposal would address the need for donors that support humanitarian programs to have access to medicines at competitive generic prices, while providing rewards to innovators.

The proposal addresses sustainability in two ways. First, it seeks to make donor markets themselves more sustainable, by increasing the feasibility of affordable supplies of second generation medicines, a necessary condition for the longer term willingness of donors to support treatment efforts. Secondly, by tying the reward system to the donor budget for medicines, it makes the reward system as sustainable as is the donor market itself.

Developing countries that do not benefit directly or extensively as grant recipients from the donor programs for HIV/AIDS, TB and Malaria or other diseases, would benefit from the initiative in the following way. The prize fund reward system would be conditioned on the patent owners granting open licenses for generic competition in all developing countries. This will create a market for generic products that is large enough to induce entry by multiple suppliers, and allow those suppliers to realize economies of scale. The combined impact of open licensing, entry by multiple suppliers and efficient economies of scale will ensure the supply of low cost versions of new medicines for developing countries.

This proposal is based on an earlier proposal presented by the governments of Barbados & Bolivia in April 2008 during the WHO Intergovernmental Working Group on Public Health, Innovation and Intellectual Property. During that process, several governments expressed support for undertaking further discussions on this proposal.

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.

There is considerable evidence that, given a large enough market, the competitive supply of generic products prices leads to lower prices for medicines.¹ There is also substantial evidence that demand in “middle income” countries is quite important, in terms of creating markets that are large enough to induce entry by several suppliers, and for those suppliers to achieve sufficient economies of scale to manufacture at the lowest unit costs.

Some drug developers refuse to license patents to generic competitors, and charge high prices for new medicines, while other drug developers voluntarily abandon monopolies in some developing country markets. Few drug developers voluntarily abandon monopolies in all developing country markets. In order to obtain low cost production of new medicines, it is important to expand the market for generic medicines beyond the markets for the poorest countries.

The rise of donor funding for some essential medicines for some health problems has encouraged greater patenting of products in developing countries. For example, patents were reportedly sought in 38 African countries, including several least developed countries (LDCs) for the one second generation HIV-AIDS drug, while an earlier product, developed by the same company before the creation of the Global Fund or PEPFAR, 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 invest their limited resources 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, to address the legitimate need for a continued pipeline of new products.

The use of Qualified Patent Pools to Support Donor Markets

The major projects and donors providing humanitarian aid in the areas of HIV-AIDS, TB, malaria and other diseases should agree upon norms for the non-exclusive voluntary licensing of product and process patents, exclusive rights in data protection and know-how. Donors will consider the use of one or more existing or new collective management mechanisms, like the patent pool that UNITAID is currently creating. These collective management mechanisms, referred to here as qualified patent pools, will address appropriate policy objectives concerning 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 qualified patent pools should offer out-licenses to generic suppliers on an open non-discriminatory basis, for use in all developing countries.

¹ See, for example, UNITAID/EB8/2008/11/1, Annex 1, Cost Benefit Analysis for UNITAID Patent Pool, 20 June 2008

Licensed Product Prize Fund

In order to create an incentive to license products, donors to humanitarian projects would be asked to set aside a fraction of their drug purchase budgets to reward developers who license innovations to qualified patent pools. One suggestion for the fraction of budgets is 10 percent of all drug purchases². This money would be placed in a Licensed Products Prize Fund.

Participation in the Licensed Product Prize Fund would be strictly voluntary. Because the rewards would only be available to products that were licensed to qualified patent pools, the incentives to license would be strong, particularly for the early entrants. Why? Consider the following stylized facts:

1. Some products will have limited patent coverage in the developing world and the prize will be the main source of revenue for innovators
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. Also, even when patents are obtained in developing countries, the cost of enforcing them can be considerable.
4. Developers of products cannot control large segments of the market where they face generic competition.
5. The Licensed Product Prize Fund would only give rewards to developers of products that license to the qualified patent pool. Generic manufacturers of inexpensive versions of the products would only benefit from the Licensed Products Prize Fund if they license new innovations to the qualified patent pools all of which may be subject to grant-back provisions benefiting the original product developer, if both parties were participating in a qualified patent pool.
6. If only a small number of firms license to the qualified patent pool, they would reap enormous returns from the Licensed Product Prize Fund.

The prize awards would 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. For example, utilization of generic copies of EFV/3TC/TDF or LPV/r would generate claims against the Licensed Product Prize Fund for the original product developers.

Developers of new products seeking prize fund payments would be asked to provide clinical evidence of the efficacy of new products, benchmarked against existing treatment options. The benefits would normally be presented in terms of estimates of Disability Adjusted Life Years (DALYS), a common pharmoeconomic metric that is used by the World Health Organization to measure the burden of disease, or Quality Adjusted Life Years (QALYS) a similar metric.

The WHO defines a disability-adjusted life year (DALY) as “a time-based measure that combines years of life lost due to premature mortality and years of life lost due to time lived in states of less than full health.” DALYS or QALYS are often used when insurance companies, employers or governments determine reimbursement policies for medicines.

² The 10% contribution is suggested as one possible funding level believed will create a big enough prize fund.

Unlike the case for some reimbursement decisions, the calculation of DALY or QALY benefits would be based upon the improvements of health outcomes, when compared to the outcome achievable from existing treatments. This reward system discourages investment in unimportant products, and encourages investments in products that truly improve health.

The prizes would be allocated in part according to a proportional reward system. To illustrate such a system, consider the follow stylized example. If one product offered a benefit of 10,000 DALYS, and another product offered benefits of 5,000 DALYS, the total DALYS benefits would be 15,000. The proportion of the prize fund that was given to the first product would be $10,000/15,000 = .67$. The proportion given to the second product would be $5,000/15,000 = .33$. In consultation with experts on pharmaceutical incentives and drug development, the Prize Fund committee could consider modifications and enhancements to this stylized approach, such as by placing a maximum cap on what any single product could receive from the fund, or awarding a premium for products that achieve other important health benefits, such as the development of antibiotics that are held in reserve for use only when first line regimes do not work.

The Licensed Product Prize Fund would make payments to developers regardless of the status of the patents, so long as the developers license whatever rights exist to a qualified patent pool. 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 important issue to be resolved would be the cases where the product developer wanted to license patent rights in some developing countries, but not in others, such as by withholding licenses in “middle income” economies. We propose to only make the Licensed Product Prize Fund rewards available to developers that licensed in all developing countries. An alternative approach would be to introduce significant reductions in the rewards for a partial rather than a full license.

The Openness Dividend.

The Licensed Product Prize Fund shall set aside up to 5 percent³ of its prize fund payments to reward parties that openly share the knowledge, materials and technology that was critical to the success of the development of the products that qualify for the prize money.

To qualify for the Openness Dividend, knowledge, materials and technology must be made freely available on a non-remunerative basis. To the extent intellectual property rights exist, the knowledge, materials and technology must be licensed on a royalty free basis for a a field of use and geographic region that is consistent with the field of use and geographic region covered by the Prize Fund rewards.

The Openness Dividend Jury System

For every licensed product that qualifies for prize rewards, an Openness Dividend Jury (ODJ) would be convened to allocate up to 5 percent of prize fund rewards related to a specific licensed product, to parties that openly shared the knowledge, materials and technology that are critical to the success of the development of the products that qualify for the prize money.

The administrators of the fund would develop agreements with a variety of academic, professional and

³ The 5% allocation is presented as a suggestion that seems an appropriate to start a discussion on incentives for collaboration and access to knowledge.

public health organizations, to act, when requested, as a pool for jury members. At the point when a licensed product became useful for the treatment of patients, and qualified for prize money, and working with conflict of interest rules, the administrators of the prize fund would call upon the relevant organizations to nominate persons for the jury, taking into consideration the expertise and independence of the jury members. The ODJ would then have no more than 120 days to receive evidence and solicit views parties that would qualify for the Openness Dividend, and to propose an allocation of the Dividend to appropriate parties. The Administrators of the Prize Fund could then accept the recommendation, or appoint a second jury to reconsider the matter.⁴ The recommendations of the juries could not be modified by the Administrators of the Prize Fund.

Open Access publishing

Articles that are published in peer reviewed journals, but which are not available in publicly accessible archives, will not be eligible for the openness dividend.

For openness dividend rewards that are associated with academic peer reviewed articles that are available in full text, with relevant materials and research, for free at the moment of publication, 10 percent of the dividend will be awarded to the publisher of the peer reviewed journal.

Benefits of the New Business Model

If product developers and donors accepted the qualified patent pool and Licensed Product Prize Fund 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/PAHO meetings on this proposal

The WHO should hold a meeting in September of 2009 to consider this proposal. Donors, Member States and interested stakeholders should be invited to participate. PAHO should organize a preliminary regional meeting in May/ June 2009 on the proposal.

⁴ The findings and determination of the second jury would be final and conclusive, except for cases of fraud, misrepresentation, or other misconduct.