

The role of prizes in stimulating R&D Comment to WHO IGWG

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Introduction

KEI notes that resolution WHA60.30 calls upon the Director General (DG) "to encourage the development of proposals . . . addressing the linkage of the cost of research and development and the price of medicines, vaccines, diagnostic kits and other health-care products."

In this regard, KEI recommends the use of monetary prizes as an alternative mechanism to stimulate private investments in R&D. Specifically, donors and governments should consider prizes as an alternative to marketing monopolies as the reward for successful investments in R&D.

This topic is addressed in more detail in a March 2007 KEI monograph on prizes (James Love and Tim Hubbard, "The Big Idea: Prizes to Stimulate R&D for New Medicines," *KEI Research Paper* 2007:1), as well in a series of blogs, papers, articles, and briefing materials available on the KEI web page, including examples of notable innovation prizes in a variety of fields, and links to articles and other research about prizes.¹

Prizes are mentioned in the July 30, 2007 draft Global Strategy and Plan of Action (the draft plan), but only as a "complementary" mechanism to stimulate R&D. If prizes are implemented as a complement to other R&D incentives, like patent or other IPR enforced monopoly marketing rights, they can be an effective incentive from the point of view of investors, but they would not ensure access to the new inventions.

As analyzed in the KEI monograph, *the Big Idea*, prizes can be implemented in many different ways, but it is recommended that, when possible, prizes be offered not as a complement, but as an alternative to monopoly marketing rights.

The key issue is the exclusive marketing right -- the monopoly -- rather than the patent system itself, since a reward system based upon prizes rather than monopolies can be implemented within the patent system, by redefining the patent as a claim against a monetary prize, rather than an exclusive right to make, market or use an invention.

As noted extensively in economics literature, the knowledge good aspect of medical inventions are potentially non-rival in consumption. Patents and other temporary monopoly privileges are granted by governments to prevent the free use of an invention in order to provide a reward for investments in R&D. These monopolies have important shortcomings. Marketing monopolies:

¹ http://www.keionline.org/index.php?option=com_content&task=view&id=4

- lead to high prices that reduce access,
- divert investments into marketing activities or "me too" copycat products, and
- are an ineffective reward for inventing and commercially developing products used primarily by poor patient groups that lack purchasing power.

A growing number of public health, economics, and innovation experts are focusing on the use of prizes as a potential alternative to marketing monopolies. Because prizes can be implemented as a reward for innovation that is not linked to the price of the product, it is an incentive mechanism that is more easily made consistent with other important policies, such as the Doha/TRIPS obligation to "promote access to medicine for all."

Implemented properly, prizes offer the potential to:

- make inventions freely available to competitive suppliers, leading to lower prices and greater access,
- avoid waste on unimportant "me too" products that do not improve health outcomes,
- reduce incentives for excessive spending on marketing and the promotion of irrational drug use, and
- stimulate R&D to benefit populations with low purchasing power.

The basic idea

As noted above, prizes are an appealing answer to a thorny dilemma. How can society ensure that knowledge goods, which are both costly to create and potentially "non-rival" in use, be shared freely? When implemented as a set of exclusive rights, the patent system is a government intervention that makes a compromise. Inventors are given temporary legal monopolies. Goods are not shared for a period of time, and then they enter the public domain. The prize system is a way of rethinking the problem. If you can divorce the incentive for innovation from the product's price to consumers, knowledge goods, including the R&D for a new medicine, can be placed in the public domain immediately, so that competition among suppliers leads to low prices and greater access to new medical inventions.

We note, of course, that the prize mechanisms should be thought of as part of a larger ecosystem of financing medical R&D, and should be implemented in combination with other instruments, such as the direct or indirect government funding of basic research, non-profit product development partnerships (PDPs), clinical trials, and other traditional and non-traditional types of funding for R&D. What the prizes offer uniquely is an alternative to the marketing monopoly as an incentive for private investment.

The challenge

The current business model for drug development, no matter how deeply flawed, is deeply embedded in our systems of governance, commerce and scholarship. Often there is almost no critical thinking about the shortcomings of or alternatives to the business model. However, the WHO IGWG on Public Health, Innovation and Intellectual Property has been asked to acknowledge the urgent need to address the shortcomings of current business models.

Resolution WHA59.24 noted "the need to promote new thinking on the mechanisms that support innovation," and Resolution WHA60.30 specifically called upon the WHO to address the "linkage" between R&D costs and prices.

If prizes replace prices as the relevant incentive, how does one determine the amount of the prize, and who pays the prize?

In many areas of the economy, there is a reluctance to abandon a system of prices determined by actual market transactions as the method of determining the value of the knowledge good, because there is a concern that prizes will be difficult to administer, or inadequately resourced.

Fortunately, there is considerable research and experience for methods of valuing the benefits of medical inventions, including pharmaceutical drugs, in part because governments, insurance companies, employers or other donors often pay or provide significant reimbursements for the purchases of medicines. The presence of third parties in financing medical purchases has led to an effort to rationalize reimbursement policies. These efforts involve the evaluation of evidence regarding health care outcomes to value new inventions.

The evaluations of the *appropriate* "prices" for medical products rely upon the same analytical tools and data that will be used determine the appropriate "prizes" for those products. In this sense, the difficulties of evaluating the value of the products are very similar. But when firms are granted a legal monopoly to sell a product, notions of fairness or rational pricing can suffer greatly, from the actions of intransigent monopoly sellers. The use of prizes rather than monopolies grants much more freedom to the parties who pay for drugs.

But given this freedom, will prizes that stimulate medical innovation be adequately resourced? This is an important challenge for policy makers, and a concern of the R&D companies. If monetary rewards from a prize mechanism are too small, they cannot be expected to attract significant levels of investment in R&D, or be taken credibly as a replacement for marketing monopolies. For these reasons, it is important to consider the incentives and obligations on governments or other stakeholders to provide sustainable funding for prize mechanisms, if they are to play an important role in stimulating innovation and ensuring access to medical inventions.

The introduction of new prize mechanisms to stimulate R&D will require effort, ingenuity and political leadership. It will be worth the trouble. Monopolies are quite harmful to the poor, and are an inefficient and deeply flawed system for promoting innovation, particularly in developing countries, where the access problems are enormous, and the prospects of high prices (and wasteful and often harmful marketing activities) do little to stimulate investments in useful innovations. The IGWG should begin the task of reinventing our systems of supporting inventive activity.

The following are several specific proposals for areas where new uses of prizes to stimulate R&D could be introduced.

Possible Implementation of Prizes

The U.S. Medical Innovation Prize Fund

The first example is not one that the IGWG will likely take up, but it is useful to discuss, because it is quite ambitious, and specified in a legislative proposal before the U.S. Congress. First introduced in the U.S. House of Representatives in 2005, and soon to be reintroduced in the U.S. Senate by Senator Bernie Sanders, the Medical Innovation Prize Fund would eliminate market exclusivity for all prescription drugs. Firms investing in R&D would no longer benefit from a temporary monopoly, but would participate in a very large fund that rewarded successful drug developers with monetary prizes. Each new successful drug would qualify for some amount of prize money. The amount of the prizes would depend upon the overall size of the fund (anticipated to be more than \$80 billion per year at current U.S. GDP levels in the Sanders proposal) and evidence of the incremental impact of a new product on health care outcomes, when compared to a benchmark (existing treatment alternatives). While every new product would be a "winner," they would also compete (in a zero sum fashion) against each other for a share of the total prize fund.

The money would be paid out over time, so there would be sufficient experience with the product to judge its efficacy. A drug developer would be eligible to participate in the reward system once a year for ten years, competing with every other firm that had developed a drug in the past 10 years for a share of the prize fund. There would be special set-asides for neglected diseases and other health care priorities.²

The U.S. proposal would feature a fixed "budget" for innovation, and a zero sum competition for a share of the innovation budget. It would co-exist with the patent system, but patents would be used to assign ownership of inventions for purposes of making claims on the prize fund, rather than enforcing a monopoly for the product. Free entry and competition among generic suppliers would drive prices down, closer to the marginal costs of production. New products would be as inexpensive to manufacture as older drugs. With prices cheap for everything, formularies for medicines would then focus on therapeutic benefits, rather than prices, of products.

If successful politically, the U.S. proposal would lead to dramatic changes in the entire global market for pharmaceutical drugs. It would create a culture of "abundance" and access for new medical inventions, while providing a sustainable and powerful reward system for the development of new products that address real health needs.

The switch to a system that promoted access to products at marginal costs would lead to changes in trade policy -- the U.S. government would no longer seek to export high prices, and instead would encourage trading partners to adopt policies that separate the markets for products from the markets for innovation.

2 The initial minimum levels of funding would be: (1) 4 percent of such amount for global neglected diseases; (2) 10 percent of such amount for orphan drugs; and (3) 4 percent of such amount for global infectious diseases and other global public health priorities, including research on AIDS, AIDS vaccines, and medicines for responding to bioterrorism.

Possible Global Application of the U.S. Medical Innovation Prize Fund

Many other countries could consider a similar approach, assuming the potential market is large enough to attract sufficient entry and competition from generic manufacturers. The U.S. domestic pharmaceutical market is huge, and it certainly could be a first mover in implementing a prize fund system. Other large markets, include the European Union or even some of its larger member states,³ Japan, Brazil, India, and China would have a sufficient domestic market to induce entry by generic drug manufactures. The European Union as a whole, after the recent expansion, is a particularly attractive place to implement the prize fund approach, because of the very large disparities in incomes between member states. Europe could have free movement of low cost generic products within the (now) 27 member union, and the elimination of price-sensitive drug formularies, in return for differential contributions to a prize fund from member states.

Smaller countries may find the prize model difficult to implement if they act alone, if they do not have sustainable sources of low-cost competitive generic products.

A voluntary prize fund funded by donors (i.e. The Global Fund/UNITAID/PEPFAR, etc) linked to licensing of inventions to a patent pool

A quite different proposed implementation involves the special and highly relevant case where the market for medicines relies upon money from foreign donors acting for humanitarian reasons. The most important example today is the commitment to addressing HIV/AIDS, tuberculosis and malaria by the Global Fund, UNITAID and the U.S. government funded PEPFAR program. The donors have a long term commitment to provide a variety of services and products, including daily treatments for HIV/AIDS for millions of persons living in developing countries.

Money for treating AIDS patients competes with the opportunities donors have to invest in non-AIDS related health care, as well as better roads and schools, infrastructure, agriculture and other development projects.

The very existence of the donor market is contingent upon prices being low enough to justify the investments in treatment. The former head of the U.S. Office of Budget and Management (OMB) Mitch Daniels once told KEI that PEPFAR would never have undertaken an initial commitment to treat AIDS patients if prices had remained above \$1,000 per year per patient. Only with generic prices falling to less than \$1 per day did the US government express interest in supporting treatment. With donors facing a crisis in the pricing of newer "second generation" HIV/AIDS drugs, the commitment by donors and hence the entire market for treatment is at risk.

Patenting for new second generation AIDS drugs is often aggressive. For example, Gilead's AIDS drug tenovofir was only patented in 2 of 99 developing countries covered by their voluntary license. But Gilead's newer drug FTC, which was registered after the creation of the Global Fund and PEPFAR, was patented in more than 47 of the 99 countries, including

3 By income.

38 countries in sub-Saharan Africa.

On the one hand, the donors who support the Global Fund, UNITAID, PEPFAR and other programs need access to inexpensive second generation AIDS drugs, but on the other hand, they don't want to undermine the systems that stimulate R&D for new AIDS drugs. The situation today is a mess. Some AIDS drugs are available for less than \$30 per year, while others are priced at thousands of dollars. Donors and drug developers both need a new business model.

One suggestion is that donors create or endorse a patent pool to manage licenses to patents needed for the manufacture of drugs to treat AIDS, TB, malaria and other target diseases or conditions, and create a prize fund to reward patent owners who license their patents to the pool.

In this proposal, the donors would commit to setting aside a fixed proportion of their budget for drug purchases to fund the prizes. One suggestion is that 10 percent of the total drug budget be set aside for the R&D prizes. *(In comparison, in 2005, total private investments in R&D were roughly 8.5 percent of global pharmaceutical sales).*

Since the prizes would only be available to patent owners who licensed patents to the patent pool, there would be an incentive to license. The first patent owners who licensed patents to the pool would receive 10 percent of the entire drug budget, even if their patents were only used in a limited number of products. As more patent owners licensed their patents to the pool, soft norms would be established, and other patent owners would be expected to follow.

The donors would send strong signals to the patent owners that they expected them to grant voluntary licenses (and sub-licenses) to the patent pool. Patent owners who refused to license to the pool could take their chances with compulsory licenses or infringement, without the political support of the donor governments.

The argument in favor of this approach is as follows.

- This is essentially a humanitarian market, that depends upon the existence of low prices for generic products.
- When possible, prices for products should approximate marginal costs, to maximize the number of patients who receive treatment.
- Drug developers should negotiate with the donors over the fraction of the budget that is paid out in prizes, and not insist on enforcement of monopolies (exclusive rights).
- Patent owners that provide voluntary licensing of patents to benefit the humanitarian effort should be rewarded -- there should be an incentive to freely license the patents to generic suppliers.
- The rewards to drug developers should be in proportion to the positive impact of the inventions on health care outcomes, in developing countries.
- By tying the funding of the prizes to the budget for drug purchases, and guaranteeing the availability of products at marginal costs, the donors would provide a sustainable and credible commitment to supporting R&D, and reconcile the need for both innovation and access.

Rapid Diagnostic Test for Tuberculosis

Tuberculosis is a deadly infectious disease. In 2005, the WHO estimated that 1.6 million persons died of TB, including many persons who are co-infected with HIV/AIDS. One of the most important health needs for the treatment of TB is the development of an inexpensive rapid diagnostic test that can be used at the point of care. Businesses normally would have weak incentives to invest in R&D for a diagnostic device that has a very low price. But an inexpensive diagnostic device is exactly what is needed to enhance the control and treatment of TB.

The creation of a prize fund for such a low cost diagnostic device would correct this market failure. The prize would make it profitable to invent something that was effectively given away for free.

One precedent for such a prize is the 2005 Grainger Challenge, managed by the U.S. National Academy of Engineering. This involved prizes of up to \$1 million for the development of economical filtration devices for the removal of arsenic from well water in developing countries. Over 70 entries were submitted, and Abul Hussan was announced the winner in 2007 for his SONO filter that has already been implemented to provide safe drinking water to 400,000 people.

Another (less successful) precedent is the 1994 Rockefeller Prize. The Rockefeller Foundation offered a prize of \$1 million for developing a low-cost highly accurate diagnostic test for gonorrhea or chlamydia that could be easily administered in the developing world - similar to the proposal for low cost rapid TB diagnostic test. The Rockefeller prize expired in 1999 without a winner, and has been critiqued for being too small, too inflexible, and offered for too short a period of time.⁴

With governments engaged, one can imagine a much large funding level for a rapid TB diagnostic test. The IGWG could undertake an investigation into the possible design and management of such a prize, and mobilize donors to fund the prize.

Prize Fund for Neglected Diseases

There is little argument that the prospect of patent enforced monopolies has done a poor job of stimulating R&D for diseases or conditions like buruli ulcer, cholera, cysticercosis, dracunculiasis (guinea-worm disease), foodborne trematode infections (such as fascioliasis), hydatidosis, leishmaniasis, lymphatic filariasis, onchocerciasis, schistosomiasis, soil-transmitted helminthiasis, trachoma and trypanosomiasis. To promote more R&D in these areas, governments and other donors need to fund a wide range of research programs, through grants and other "push" mechanisms. There is, however, an important role for incentives that attract and reward businesses that invest in successful product development.

At present, the Bill and Melinda Gates Foundation has become an important funder of research in neglected diseases, but there is a need for governments to provide the sustainable sources for finance for R&D.

⁴ For this and other examples, see: Benjamin Krohmal, Prominent Innovation Prizes and Reward Programs, KEI Research Note 2007:1, March 1, 2007.

A prize fund to reward the successful development of new treatments for neglected diseases would enhance other public sector and private donor efforts to stimulate R&D. In this regard, KEI and others have recommended the a mechanism, like the Sanders bill in the United States, that rewards drug developers with monetary prizes that are based upon the impact of the invention in improving health care outcomes. Like the Sanders proposal, the funds could be divided among successful drug developers according to the relative benefits that each product provides, and the competition to supply better health care outcomes would determine the size of the prizes for particular inventions.

Here, as elsewhere, we would tie eligibility for the prize to the licensing of the inventions to a patent pool that facilitated generic competition for the products.

Other possible areas to use prizes

There are many other areas were the IGWG could consider prizes to stimulate new R&D. These would include efforts to reward open source research, such as the Gotham Prize for Cancer Research, which was established "to encourage new and innovative approaches to cancer research by fostering collaboration among top thinkers in the field--with the goal of leading to progress in the prevention, diagnosis, etiology and treatment of cancer," the Prize for Life, an effort to accelerate treatments for Amyotrophic Lateral Sclerosis (ALS), or the 2006 Archon X Prize for Genomics, which offers \$10 million for reaching targets for high speed and low cost in full genome sequencing, to mention a few.

Patent Buy-outs and Advance Marketing Commitments

Closely related to prizes are proposals for patent buy-outs or advanced marketing commitments (AMCs). Voluntary prize mechanisms that are linked to the licensing of inventions to patent pools are very similar to proposals for patent buy-outs. Both seek to expand access to inventions. If the funding for the patent buy-out program is known in advance of the existence of the invention, it acts like a prize. AMCs are often presented in the context of a monopoly supplier.