

Views on Development

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Results Based Financing: The 'Health Impact Fund' as an example for smart pro-poor innovations

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The poverty endured by the bottom half of humankind poses serious dangers to their health and survival. The poor bear a hugely disproportional burden of disease and a hugely disproportional share of premature deaths: 30 per cent of all deaths each year, 18 million, are from poverty-related causes. These much greater burdens of morbidity and premature mortality in turn entail large economic burdens that keep most of the poor trapped in lifelong poverty.

To reduce the global burden of disease ('GBD'), we have to reform the way the development of new medical treatments is funded. I will sketch a concrete, feasible, and politically realistic reform plan that would give medical innovators stable and reliable financial incentives to address the diseases of the poor. If adopted, this plan would not add much to the overall cost of global health-care spending. In fact, the reform would actually pay for itself. Moreover, it would distribute the cost of global health-care spending more fairly across countries, across generations, and between those lucky enough to enjoy good health and the unlucky ones suffering from serious medical conditions.

The global patent system doesn't serve the poor

With medicines, the fixed cost of developing a new product is extremely high for two reasons. It is very expensive to research and refine a new medicine and then to take it

through elaborate clinical trials and national approval processes. Moreover, most promising research ideas fail somewhere along the way and thus never lead to a marketable product.

The conventional way of preventing the looming undersupply is to reward innovators with patents that entitle them to bar others from producing or distributing the innovative product and to waive this entitlement in exchange for a licensing fee. The result of such market exclusivity is an artificially elevated sales price that, on average, enables innovators to recoup their R&D investment through selling products that, even at prices far above marginal cost, are in high demand.

This restraint hurts generic producers and it also hurts consumers by depriving them of the chance to buy such medicines at competitive market prices. But consumers also benefit from the impressive arsenal of useful medicines whose development is motivated by the prospect of patent-protected mark-ups.

It may seem obvious that this benefit outweighs the loss of freedom caused by patents. But not everyone is either affluent enough to buy advanced medicines at very high prices or fortunate enough to need them only after patent expiration. The poor derive no benefit from patented medicines because they cannot get access to them. The loss of freedom patents inflict on the global poor – and they number in the billions – is a huge

loss in terms of disease and premature death. There is no associated gain that could compensate those suffering these losses; and the gains that patents bring to the affluent cannot possibly justify these losses either.

Until the 1990s, strict patent rules were mostly confined to the affluent states, which allowed the less-developed countries to have weaker patent protections or none at all. This had little effect on innovation, but the exemption brought relief to many who could obtain medicine at a competitive market price. But in the 1990s a powerful alliance of industries induced wealthy states to press strong, globally uniform intellectual property rules upon the world. Acceptance of this regime, enshrined in the *Trade-Related Aspects of Intellectual Property Rights Agreement* of 1994 ('TRIPS'), was made a condition of World Trade Organization ('WTO') membership, which, it was then promised, would allow poor countries to reap large benefits from trade liberalisation. While the affluent states have been slow to lower their trade barriers and subsidies, they have worked hard toward implementing intellectual property rights in the less-developed countries – with devastating effects, for instance, on the evolution of the HIV/AIDS epidemic.

The world responds to the catastrophic health crisis in a variety of ways, including efforts to fund delivery of medicines to the poor and to foster the development of new medicines for the diseases of the poor. But these efforts are not nearly sufficient to protect the poor. We need a systemic solution that addresses the global health crisis at its root. Involving institutional reform, such a systemic solution is politically more difficult to achieve. But, once achieved, it is also politically much easier to sustain.

Which are the drawbacks of the globalised patent regime?

- **High Prices.** While a medicine is under patent, it will be sold near the profit-maximising monopoly price, high above the cost of production. With patented medicines, mark-ups in excess of 1,000 per cent are not exceptional.

- **Neglect of Diseases concentrated among the Poor.** Diseases concentrated among the poor – no matter how widespread and severe – are not attractive targets for pharmaceutical R&D. Companies predictably prefer even the trivial ailments of the affluent, such as hair loss and acne, over tuberculosis and sleeping sickness. Only 10 per cent of all pharmaceutical research focuses on diseases that account for 90 per cent of the GBD.
- **Bias toward Maintenance Drugs.** Under the existing patent regime, maintenance drugs are far more profitable than curative or preventative medicines, making patients buy the medicine week after week, year after year. Vaccines are least lucrative, but the health benefits of vaccines tend to be exceptionally great as vaccines protect from infection or contagion not merely each vaccinated person but also their contacts. Once more, then, the present regime guides pharmaceutical research in the wrong direction – and here to the detriment of poor and affluent alike.
- **Wastefulness.** Innovators bear the cost of filing for patents in dozens of national jurisdictions and of monitoring these countries for possible infringements of their patents. Huge amounts are spent on costly litigation that pits generic companies, with strong incentives to challenge any patent on a profitable medicine, against patentees, whose earnings depend on their ability to defend, extend, and prolong their patent-protected mark-ups.
- **Counterfeiting.** Large mark-ups also encourage the illegal manufacture of fake products. Such counterfeits often endanger patient health. They also contribute to the emergence of drug-specific resistance, when patients ingest too little of the active ingredient of a diluted drug. The emergence of highly drug resistant disease strains – of tuberculosis, for instance – poses dangers to us all.
- **Excessive Marketing.** With a very large mark-up, it seems rational to make extensive efforts to increase sales volume. This produces pointless battles over market share among similar ('me too') drugs as well as perks that induce doctors to prescribe medicines even when these are not indicated or when competing medicines are likely to do better. It also pays to fund massive direct-to-consumer advertising

that persuades people to take medicines they do not really need.

- **The Last-Mile Problem.** Even in affluent countries, pharmaceutical companies have incentives only to sell products, not to ensure that these are actually used, properly, by patients whom they can benefit. This problem is compounded in poor countries, which often lack the infrastructure to distribute medicines as well as the medical personnel to prescribe them and to ensure their proper use.

Some governments have issued or threatened to issue compulsory licenses in order to gain for their population cheaper access to patented medicines. But this may be counterproductive. By issuing such license, a government authorises the production and marketing of a cheaper generic version of a patented medicine on condition that the authorised generic firm pays a small license fee to the patentee. The license, and even the mere threat of one, will typically cause the price of the relevant medicine to fall substantially in the relevant country. But this welcome relief from the problem of high prices aggravates the neglect of diseases concentrated among the poor. Pharmaceutical companies spend less on the quest for vital medicines when the uncertainties of development, testing, and regulatory approval are compounded by the additional unpredictability of whether successful innovators will be allowed to recoup their R&D investments.

We must find another way of funding pharmaceutical innovation

Counterproductive effects notwithstanding, the moral appeal of compulsory licensing is compelling. What do we say to patients who are suffering and dying even though they could obtain the medicine if sales price were near cost? This question becomes even more pressing when we realise that including the poor adds nothing to the cost of innovation.

It is indisputable that powerful new medicines whose development was motivated by the hope for profits have greatly benefited some patients: namely those affluent enough to buy them at monopoly prices or fortunate enough to need them after patent expiration. If all human beings were so affluent or fortunate, then patents might be defensible as in everyone's best interest. However, many human beings are trapped in severe poverty. Most of them derive little or no benefit from the marvellous arsenal of available medicines. The

often devastating cost is imposed on them by others who, for their own advantage, interpose the barrier of patents between poor people and the generic companies willing to supply the medicines they urgently need. This interposition is a grievous injustice that kills millions of poor people each year.

If rich countries and their citizens desire medical innovation, then they must find other ways of funding. The problem here is that allowing the poor their freedom of access at competitive market prices substantially reduces the monopoly rents that can be extracted from affluent patients and thereby also the incentives of pharmaceutical companies to make large R&D investments in the first place. Since there are substantial problems with splitting markets with large price differentials, it is best to level pharmaceutical prices in the opposite direction: instead of unjustly imposing monopoly prices also on the poor, we should grant open access at competitive market prices also to the affluent. In this way, we avoid the problem of high prices in an efficient way. We also eliminate high mark-ups entirely and thereby avoid the problems associated therewith: wastefulness, counterfeiting, excessive marketing, and the bias toward maintenance drugs.

Because pharmaceutical R&D is urgently needed, loss of funding from patents must be replaced somehow – with public funds – to ensure a reliable innovation flow long-term. Such public funding can be designed to overcome the two last remaining problems of the present regime: the neglect of diseases concentrated among the poor and the last-mile problem.

The way to go: incentives for global health impacts

We need a straightforward and moderate reform that creates a supplementary mechanism to the current regime that, by addressing the needs of the poor, would remedy the injustice now imposed upon them. Let me outline a reform proposal that comprises six elements.

First, just as the patent regime provides a *general* innovation incentive, so should its complement by rewarding any successful new medicine, in proportion to its success.

Second, while the patent regime rewards medicines on the basis of the market demand, thereby effectively excluding the poor, its complement gives equal standing to all by

defining success simply in terms of human health. On this complementary track, the success of a medicine is assessed by the reduction in human morbidity and premature mortality it achieves – regardless of whether these harms are averted from rich or poor patients.

Third, in order to help overcome the last-mile problem, the rewards available under the complementary mechanism should be tied not to what a medicine can do, but to what it *actually* achieves in the world.

Fourth, when such a general mechanism provides large enough health impact rewards, it will attract sufficient innovation and sufficient efforts to ensure real access to new medicines worldwide. This avoids any need for compulsion. Innovators can be left free to choose between the two tracks, developing on the new track high-impact medicines needed also by many poor patients and on the conventional patent track low-impact medicines desired by the more affluent.

Fifth, in order to reinforce the incentive toward facilitating real access, health impact rewards should be conditional on the medicine being priced no higher than the lowest feasible cost of production and distribution.

Sixth, health impact rewards should be funded by governments as a public good. In order to minimise burdens and deadweight losses due to taxes, the cost should be spread as widely as possible. This suggests that the complementary funding mechanism should be global (rather than national) in scope. Global scope also brings huge efficiency gains by diluting the cost of the scheme without diluting its benefits: the cost of achieving an innovation remains the same even while its aggregate benefit increases with the number of beneficiaries. Finally, an international agreement would also reinforce the commitment of individual countries to the scheme.

Pharmaceutical innovation is therefore best encouraged by promising to reward any safe and effective new medicine in proportion to its *global* health impact, including not merely all diseases but also all patients.

A concrete proposal: rewarding pharmaceutical innovation by impact, with the Health Impact Fund

The proposal is then for the creation of a new international agency that offers to reward any new medicine based on its health impact during its first decade or so. This *Health Im-*

pact Fund ('HIF') would provide ample rewards for the development of new high-impact medicines without excluding the poor from its use.

The HIF would be a pay-for-performance mechanism that offers innovators the option (!) to register any new medicine. The innovator would agree to make it available, during its first decade on the market, at no more than the lowest feasible cost of production and distribution (to be determined through competitive tenders submitted by generic manufacturers). The innovator would further agree to allow, at no charge, generic manufacture and distribution afterwards. In exchange, the registrant would receive, during that first decade, annual reward payments based on its product's therapeutic benefits. Each year, the HIF would divide its annual reward pool among all registered products in proportion to their assessed health impact in that year.

This way, the HIF would provide a solution to the problems described above. It would foster the introduction of new high-impact medicines, especially against the long-neglected diseases of the poor, and facilitate access to registered products by tightly limiting their price. It would also motivate registrants to ensure that their products are widely available, competently prescribed and optimally used. The HIF assesses health impact without regard to whether it is achieved through cure, symptom relief, or prevention. There would be little costly litigation as generic competitors would lack incentives to compete and innovators would have no incentive to suppress generic products (because they enhance the innovator's health impact reward). Counterfeiting of HIF-registered products would be unattractive. Excessive Marketing would also be much reduced and confined to marketing resulting in measurable therapeutic benefits. Incentives to develop me-too drugs to compete with an existing HIF-registered medicine would be weak.

The HIF can provide optimal innovation incentives only if potential registrants are assured that the HIF will continue to have annual rewards pools to distribute throughout the decade following market approval. The funding is therefore best guaranteed by a broad partnership of countries. If all countries agreed to contribute just 0.01 percent (1 euro of every 10,000) of their gross national incomes forward-going, then the HIF could get started with nearly 5 billion euros annually, which is a reasonable minimum. To provide

stable incentives, member states must guarantee funding some 15 years into the future.

The HIF sustains an enduring competition among innovators, with earnings tied to impact on health. Health impact can be measured in quality-adjusted life years (QALYs) saved. The QALY metric has been refined over the last 20 years and is already extensively used by insurers in deciding which new drugs to cover. Taking as baseline the pharmaceutical arsenal before a registered medicine was introduced, the HIF would estimate to what extent this medicine has added to the length and quality of human lives. Estimates would be imperfect — but they would achieve a vastly better correlation between profits and actual health impact than the current system.

Conclusion

The creation of a mechanism like the HIF would be an important structural reform lifting huge burdens of disease and insecurity from the poor and thereby empower them to take a more active role in their further political and social emancipation.

Efforts encouraged by HIF rewards would not be neatly confined to new medicines. Once a firm has registered a new drug, its reward will depend on its impact, which will depend on many factors some of which – for example, the quality of health-care delivery in poor countries – the firm can affect. By helping to improve such health-care delivery, an innovator can magnify its medicine's impact and reward.

Moreover, new medicine and effective delivery should complement other efforts such as securing access to clean drinking water or the like. We can think of this scheme as one central module of a larger health reform project. Once this central module is specified and implemented, it can certainly be extended to other social factors essential to human health. It makes sense, nonetheless, to begin with this module as a useful new paradigm. This paradigm could also be replicated in other domains, such as agriculture and green clean technologies, where the current patent system also leads to the inefficient underutilization of beneficial innovations to the detriment especially of the poor. ■