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#### ABSTRACT

Pricing advanced medicines beyond the reach of the poor and encouraging neglect of diseases concentrated among them, the TRIPS Agreement produces avoidable death and disease on a massive scale. This injustice can be remedied through a Health Impact Fund that gives patent holders the option to price any new medicine at cost in exchange for annual reward payments based on this medicine's global health impact.

Original in English.

#### KEYWORDS

Advance Market Commitment — Disease — Health Impact Fund — Incentives — Justice — Medicine — Monopoly — Patent — Poverty — Public good — Research — Rights — TRIPS



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# MEDICINES FOR THE WORLD: BOOSTING INNOVATION WITHOUT OBSTRUCTING FREE ACCESS

Thomas Pogge

## Background

In an earlier essay for *SUR Journal*,<sup>1</sup> I have described the radical inequality blighting our world. At current exchange rates, the poorest half of the world's population — some 3,400 million people — has less than 2% of global income as against 6% of global income received by the most affluent one percent of US households which consist of only 3 million people.<sup>2</sup> The bottom half of humankind owns about 1% of all global wealth as against 3% owned by the world's 946 billionaires.<sup>3</sup> These inequalities among individuals are staggering. And they continue to increase rapidly, not only globally,<sup>4</sup> but also within most countries. In the US, for example, the bottom half of the population saw its share of national income decline from 26.4% to 12.8% during 1979-2005, while those in the top one percent of the income hierarchy expanded their share from 9% to 21.2%.<sup>5</sup> In China during 1990-2004, the income share of the bottom half declined from 27% to 18%, while that of the top tenth increased from 25% to 35%.<sup>6</sup> In recent decades, income inequality has been clearly declining in only four countries. Brazil is one of these four, but still among the most inegalitarian societies with the bottom half earning only 14% of all household income as against 45% for the top tenth.<sup>7</sup>

Such huge inequalities are especially remarkable when those at the bottom lack not merely pocket money, denying them the toys of the rich,

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*Notes to this text start on page 137.*

but access to the most basic necessities of human life. And this is actually the case, both globally and in most countries. The poverty endured by the bottom half of humankind poses serious dangers to their health and survival. The poor worldwide face greater environmental hazards than the rest of us: from contaminated water, filth, pollution, worms and insects. They are exposed to greater dangers from people around them: through traffic, crime, communicable disease, and the cruelties of the more affluent. They lack means to protect themselves and their families against such hazards: through clean water, nutritious food, good hygiene, ample rest, adequate clothing, and safe shelter. They lack the means to enforce their legal rights or to press for political reform. They are often obliged by dire need or debt to incur additional health risks: by selling a kidney, for instance, or by accepting hazardous work in prostitution, mining, construction, domestic service, textile and carpet production. They lack financial reserves and access to public sources of medical knowledge and treatments, and therefore face worse odds of recovering from disease. Mutually reinforcing, all these factors ensure that the poor bear a hugely disproportional burden of disease — especially of communicable, maternal, perinatal and nutritional conditions — and a hugely disproportional share of premature deaths: One third 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.

This cycle of mutually reinforcing poverty and disease can be broken by reducing or eradicating severe poverty. I have argued that this can be done effectively by reforming various features of existing global institutional arrangements that — beneficial to the affluent and maintained by them — contribute greatly to the persistence of poverty.<sup>8</sup> But it is also possible to make substantial progress against the global burden of disease (GBD) more directly: existing huge mortality and morbidity rates can be dramatically lowered by reforming 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, on any plausible accounting, which would take note of the huge economic losses caused by the present GBD, the reform would actually save money. 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 Problem

Medical progress has traditionally been fueled from two main sources: government funding and sales revenues. The former — given to universities, corporations, other research organizations and governmental research facilities such as the US National Institutes of Health — has typically been *push* funding focused on basic research. Sales revenues, usually reaped by corporations, have mostly funded more applied research resulting in the development of specific medicines. Sales revenues, by their nature, constitute *pull* funding: an innovation has to be developed to the point of marketability before any sales revenues can be realized from it.

The fixed cost of developing a new medicine 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. Both factors combine to raise the research and development (R&D) cost per new marketable medicine to somewhere around half a billion dollars or more. Commencing manufacture of a new medicine once it has been invented and approved is cheap by comparison. Because of this fixed-cost imbalance, pharmaceutical innovation is not sustainable in a free market system: competition among manufacturers would quickly drive down the price of a new medicine to near its long-term marginal cost of production, and the innovator would get nowhere near recovering its R&D investment.

The conventional way of correcting this market failure of undersupply is by awarding innovators intellectual property rights that entitle them to bar competitors or to charge them licensing fees. Either way, the result of such monopolies is an artificially increased sales price that enables innovators to recoup their R&D expenses through selling products that, even at prices far above marginal cost, are in heavy demand.

Monopolies are generally denounced by economists as inefficient and by ethicists as an immoral interference in people's freedom to produce and exchange. In the case of patents, however, many believe that the curtailment of individual freedom can be justified by the benefit, provided patents are carefully designed. One important design feature is that patents confer only a temporary monopoly. Once the patent expires, competitors can freely enter the market with copies of the original innovation and consumers need no longer pay a high mark-up over the competitive market price. Temporal limits make sense because additional years of patent life barely strengthen innovation incentives: At a typical industry discount rate of 11% per annum, a 10-year patent life delivers 69%, and a 20-year patent life 90%, of the profit (discounted to present

value) that a permanent patent would deliver.<sup>9</sup> It makes no sense to impose monopoly prices on all future generations for the sake of so slight a gain in innovation incentives.

During the life of the patent, everyone is legally deprived of the freedom to produce, sell and buy a patented medicine without permission from the patent holder. This restraint hurts generic producers and it also hurts consumers by depriving them of the chance of buying such medicines at competitive market prices. Still, consumers also benefit from the impressive arsenal of wonderful medicines whose development is motivated by the prospect of monopoly rents.

It may seem obvious that this benefit outweighs the loss of freedom. But we must consider that not everyone is either affluent enough to buy advanced medicines at monopoly prices or fortunate enough to need them only after patent expiration. Many human beings are trapped in severe poverty. Most of them derive little or no benefit from that marvelous arsenal because they cannot, at prevailing prices, get access to the medicines they need. These people — and they number in the billions — have a powerful objection to the use of monopoly patents for incentivizing pharmaceutical innovation: “if the freedom to produce, sell and buy advanced medicines were not curtailed, then the affluent would need to find another (for them possibly less convenient) way of funding pharmaceutical research. But advanced medicines would then be available at competitive market prices, and we would have a much better chance to get access to them through our own funds or with the help of national or international government agencies or nongovernmental organizations. The loss of freedom imposed through monopoly patents thus inflicts on us a huge loss in terms of disease and premature death. This loss cannot possibly be justified by any gain that monopoly patents may bring to the affluent”.

This objection was less pertinent until the 1990s, when 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 exemption of poor countries had little effect on innovation incentives because, in these countries, those able to afford advanced medicines at monopoly prices are few, relative to the one-billion population of the high-income countries. But the exemption brought relief to many poor residents of poor countries: to all those who obtained at competitive market prices advanced medicines they would not have been able to obtain at the much higher profit-maximizing monopoly price.

This diversity of national regulations was destroyed in the 1990s when a powerful alliance of industries (software, entertainment, pharma, and agribusinesses) pressured the governments of the richest states to force uniform intellectual property rules upon the world. Acceptance of this regime, enshrined in the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement

of 1994, was made a condition of the World Trade Organization (WTO) membership which, it was then promised, would allow the poor countries to reap large benefits from trade liberalization. This promise was broken as the high-income countries continue to sabotage the export opportunities of poor countries through a variety of protectionist measures. But the globalization of uniform intellectual property rights is prosecuted relentlessly — with devastating effects, for instance, on the evolution of the AIDS epidemic.

The world responds to the catastrophic health crisis among the global poor in a variety of ways: with the usual declarations, working papers, conferences, summits, and working groups first and foremost, of course; but also with efforts to fund delivery of medicines to the poor through *intergovernmental initiatives* such as 3 by 5,<sup>10</sup> through *governmental programs* such as the US President's Emergency Plan for AIDS Relief (PEPFAR), through *public-private partnerships* like the Global Alliance for Vaccines and Immunization (GAVI) and the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM), and through medicine donations from pharmaceutical companies; and with various efforts to foster the development of new medicines for the diseases of the poor, such as the Drugs for Neglected Diseases Initiative (DNDi), the Institute for One World Health, the Novartis Institute for Tropical Diseases, and various prizes as well as advance purchase commitments and advance market commitments.<sup>11</sup>

Such a busy diversity of initiatives looks good and creates the impression that a lot is being done to solve the problem. And most of these efforts are really doing good by improving the situation relative to what it would be otherwise. Still, these efforts are not nearly sufficient to protect the poor. It is unrealistic to hope that enough billions of dollars will be devoted to neutralizing the cost imposed on the world's poor by the globalization of monopoly patents. And it is even more unrealistic to hope that such billions will reliably and efficiently be spent year after year. It makes sense then to look for a more 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 maintain. And it preempts most of the huge and collectively inefficient mobilizations currently required to produce the many stop-gap measures, which can at best only mitigate the effects of structural problems they leave untouched.

The quest for such a systemic solution should start from an analysis of the main drawbacks of the newly globalized monopoly patent regime.

**High prices.** While a medicine is under patent, it will be sold at the profit-maximizing monopoly price which is largely determined by the demand curve of the affluent. When wealthy people really want a drug, then its price can be raised quite high above the cost of production before increased gains from

enlarging the mark-up are outweighed by losses from reduced sales volume. With patented medicines, mark-ups in excess of 1000% are not exceptional.<sup>12</sup> When such high monopoly prices prevail, the poor can have access only through the charity of the affluent.

**Neglect of diseases concentrated among the Poor.** Under a monopoly patent regime, such diseases — no matter how widespread and severe they may be — are not lucrative targets for pharmaceutical R&D. This is so because the demand for such a medicine drops off very steeply as the patent holder enlarges the mark-up. There is no prospect, then, of achieving high sales volume *and* a large mark-up. Moreover, there is the further risk that a successful research effort will be greeted with loud demands to make the medicine available at marginal cost or even for free, which would force the innovator to write off its R&D cost as a loss. In view of such prospects, biotechnology and pharmaceutical companies predictably prefer even the trivial ailments of the affluent, such as hair loss and acne, over tuberculosis and sleeping sickness. This problem of neglected diseases is also known as the 10/90 problem, alluding to only 10% of all pharmaceutical research being focused on diseases that account for 90% of the GBD.

**Bias toward symptom relief.** Medicines can be roughly sorted into three categories: curative medicines remove the disease from the patient's body; symptom-relieving medicines improve well-being and functioning without removing the disease; preventative medicines reduce the likelihood of contracting the disease in the first place. Under the existing monopoly patent regime, symptom-relieving medicines are by far the most profitable, with the most desirable patients being ones who are not cured and do not die (at least until after patent expiration). Such patients buy the medicine week after week, year after year, delivering vastly more profit than would be the case if they derived the same health benefit from a cure or vaccine. Vaccines are least lucrative because they are typically bought by governments, which enjoy a strong bargaining position. This is highly regrettable because 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.<sup>13</sup> Once more, then, the present regime guides pharmaceutical research in the wrong direction — and here to the detriment of poor and affluent alike.

**Wastefulness.** Under the present regime, innovators must bear the cost of filing for patents in dozens of national jurisdictions and then also the cost of monitoring these jurisdictions for possible infringements of their patents. Huge amounts are spent in these many jurisdictions on costly litigation that pits generic companies, with strong incentives to challenge any patent on a successful medicine, against patent holders, whose earnings depend on their ability to defend, extend, and prolong their monopoly rents. Even greater costs are due

to the deadweight loss (DWL) “on the order of \$200bn” that arises from blocked sales to buyers who are willing and able to pay the competitive market price but not the much higher monopoly price.<sup>14</sup>

**Counterfeiting.** Very large mark-ups also encourage the illegal manufacture and sale of medicines. Even when such illegal drugs are pharmacologically fully equivalent, they reduce innovator profits and thereby undermine R&D incentives. When they are not fully equivalent (e.g., diluted, adulterated, inert, or even toxic), they endanger patient health.

**Excessive marketing.** When pharmaceutical companies can maintain a very large mark-up, they find it rational to make extensive special efforts to increase sales volume by influencing physicians’ prescription patterns. This produces pointless battles over market share among similar (“me-too”) drugs as well as gifts that induce doctors to prescribe medicines even when these are not indicated or when competing medicines are likely to do better. With a large mark-up it also pays to fund massive direct-to-consumer advertising that persuades people to take medicines they don’t really need for diseases they don’t really have (and sometimes for invented pseudo-diseases).<sup>15</sup>

**The last-mile problem.** While the present regime provides strong incentives to expose affluent people to patented medicines they do not need, it provides no incentives to ensure that poor people benefit from medicines they do need. Even in affluent countries, pharmaceutical companies have incentives only to sell products, not to ensure that they are actually taken, properly, by patients whom they can benefit. This issue is compounded in poor ones, where the infrastructure is severely lacking to distribute, prescribe, and supervise the proper consumption of medicine. In fact, the present regime gives pharmaceutical companies the opposite incentives. To profit under this regime, a company needs not merely to develop and patent a medicine that is effective in protecting paying patients from a disease and/or its detrimental symptoms. It also needs this target disease to thrive and spread because, as a disease waxes or wanes, so does market demand for the remedy. A pharmaceutical company making a morally motivated effort to allow the poor to benefit from its patented medicine would be seriously undermining its economic position: by paying for the effort to make its drug competently available to poor patients, by curtailing a disease on which its profits depend, and by losing affluent customers who find ways of buying, cheaply, medicines meant for the poor.

Contemplating these seven problems together, we see another reason to aim for a comprehensive solution in preference to the many stopgap measures that have been proposed and sometimes (at least partially) implemented: The practical value of efforts to mitigate one of the seven problems may be greatly reduced by one of the other problems that remains unaddressed; and efforts to mitigate one problem may aggravate another. For example, a drug donation

for the benefit of the poor, intended to mitigate the problem of high prices, may actually do more harm than good because of the weak health infrastructure (last-mile problem) in the recipient countries. Lacking competent medical instruction and package inserts in their own language, poor patients may fail to take the medicine in the right doses, at the right times, or for the appropriate length of time. Such patients may not merely remain sick; they may also develop and spread drug-resistant strains of the disease which (as in the case of MDR and XDR tuberculosis) can pose grave dangers to people everywhere.

Another example of counterproductivity is compulsory licenses that some governments have issued or threatened in order to gain for their populations cheaper access to patented medicines. Though specifically permitted by the TRIPS Agreement as reaffirmed in the Doha Declaration,<sup>16</sup> compulsory licenses are energetically resented by pharmaceutical companies, and governments daring to issue such licenses are routinely censured and penalized by these companies and by the rich-country governments doing their bidding. By issuing a compulsory license, a government authorizes the production and marketing of a cheaper generic version of a patented medicine on condition that the authorized generic firm pays a small license fee to the patent holder. Such a 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 also aggravates the neglect of diseases concentrated among the poor. Pharmaceutical companies spend less on the quest for vital medicines — especially ones needed mainly by the poor — when the uncertainties of development, testing, and regulatory approval are compounded by the additional unpredictability of whether and to what extent successful innovators will be allowed to recoup their investments through undisturbed use of their monopoly pricing powers.

## Reasoning

Counterproductive effects notwithstanding, the moral appeal of compulsory licensing is compelling. Consider a life-saving medicine whose patent-holding producer sells it at \$100, of which \$10 constitutes the long-run marginal cost of production and distribution. The high sales price effectively excludes poor patients many of whom, if the sales price were near cost, could gain access to the medicine, with the help of some international organization, perhaps, or on their own. What do we say to these patients who are suffering and dying even though they could obtain the medicine at the competitive market price? We tell them that, to merit access, they must pay not merely for the physical medicine but also for the intellectual property embodied in it: for the innovative idea or discovery or invention. But how can we impose such a huge mark-up

for intellectual property on them, and thereby effectively exclude them from the medicine, when the cost to them of exclusion is sickness and death?

This question becomes even more pressing when we realize that including the poor adds nothing to the cost of innovation. It is a wonderful thing about the products of thought that their cost is independent of the number of beneficiaries. The intellectual labors of composing a novel are exactly the same, regardless of whether it has millions of readers or none at all. Likewise for the labors of producing music, composing software, developing a new breed of plant or animal, and discovering a new medically effective type of molecule. Millions can benefit from such intellectual efforts without adding at all to their cost.<sup>17</sup> And this renders morally irresistible the conclusion that poor people, when their lives are at stake, must not be prevented from buying medicine from willing suppliers at competitive market prices. A compulsory license secures this freedom for the poor.

But what about the person or company that has put in the effort and expense to achieve the innovation? Doesn't the innovation belong to him or her or it — to give or withhold or sell at will? Many believe that there is such a natural right of first appropriation, analogous to the right of someone who takes possession of unowned objects such as apples or wood or water in a state of nature as Locke has described. But the analogy is deeply flawed: the person who appropriates some apples does not thereby deprive others of the opportunity to do likewise. To be sure, no one else can eat the particular apples she has eaten. But, if she leaves “enough and as good” for others (as Locke and Nozick require) then others can collect and eat other apples.

As Nozick emphasizes, a medical researcher who synthesizes a new medicine from widely available materials and refuses to share this medicine with others or to show them how to make it, such a researcher is also leaving enough and as good. He does not interfere with the freedom of others to acquire the same materials and chemically to transform them into the lifesaving medicine if they can. He merely refuses to help them.<sup>18</sup>

Nozick's argument may be sound, but it is of no help in the defense of intellectual property. Here the question is whether the medical researcher is entitled also to veto production of the medicine by others who learn how to make it later. Demanding such veto power, the medical researcher asserts a natural right of ownership not over object *tokens* he has produced, but over an object *type*: a whole species of medically effective molecule. In doing so, he is like someone who, based on having first conceived the idea of eating apples, claims ownership of this idea and thus asserts that it is up to her to give or withhold or sell at will her permission to the apple-eating of others. This appropriation of a *type* is not supported by Locke's view. On the contrary, it clearly goes against Locke: enforcing an innovator's exclusive property right

over all objects of a class necessarily fails to leave enough and as good for everyone else and partially expropriates others who lose the freedom to use their own apples for eating or the freedom to transform their own materials in a certain way. It necessarily deprives others of the freedom the innovator claims for himself: the freedom to eat apples legitimately acquired, or to produce certain molecules out of legitimately acquired materials, without another's permission. Far from supporting monopoly rights in pharmaceuticals, the philosophical tradition most friendly to property rights thus refutes such intellectual property rights. Generic producers have a natural right to do what the innovator did before them: to produce, if they can, medicine from ingredients they legitimately own and to offer such medicine for sale. And patients have a natural right to purchase such medicine from generic suppliers on mutually agreeable terms.<sup>19</sup>

But is not such freedom on the part of patients and generic producers destructive of innovation? Does it not deprive us of the wonderful new medicines pharmaceutical innovators keep on producing? These questions constitute a change of venue, suggesting a defense of monopoly patents not in the courtroom of natural rights but in the courtroom of mutual advantage. Does this defense succeed? It is indisputable that wonderful 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 monopoly patents might be defensible as in everyone's best interest: it would then be rational for all of us to accept the cost of laying down our rights to produce, sell, and buy a new medicine invented by another in exchange for the much greater benefit of having available a broad and powerful arsenal of pharmaceuticals.

In fact, however, many human beings are trapped in severe poverty. Most of them derive little or no benefit from the marvelous arsenal of available medicines because they cannot, at prevailing prices, get access to them. For these people — and they number in the billions — it would be highly irrational to agree to lay down their freedom so that the affluent can more successfully use monopoly patents to stimulate pharmaceutical innovations.<sup>20</sup> In the real world, the poor do not give such highly irrational consent. The often devastating cost is imposed on them by others who, for their own advantage, interpose the barrier of monopoly 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.<sup>21</sup>

This injustice is manifest in national legislation — in India, for instance, where the poor have recently lost their legal freedom of access to medicines at competitive market prices. It is also manifest in international trading rules such as the TRIPS Agreement, which required India to implement the legislative

changes as a condition of the limited access WTO membership affords Indian exporters to the markets of the affluent countries. Perhaps the governments of India and other less developed countries made a reasonable choice when they imposed unjust pharmaceutical access rules upon their poor for the sake of gaining a little more fairness in international trade.<sup>22</sup> But the powerful affluent countries devising and imposing the present WTO regime have no such excuse. They are acting most unjustly by pressing weaker countries to inflict this injustice on their poor. If rich countries and their citizens desire medical innovation, then they must find ways of funding it that either leave the freedom of the poor unreduced or else adequately compensate the poor for the loss of freedom imposed upon them.

Because adequately compensating poor people for disease and death is more costly and often impossible, let us consider ways of funding pharmaceutical innovation that do not deprive the poor of their freedom of access to existing medicines at competitive market prices. This freedom is inconvenient for the affluent by making it difficult to collect monopoly rents from anyone. Though the affluent are often willing to buy advanced medicines at prices far above the marginal cost of production, many of them prefer to buy cheaper, even illegally. And clever brokers and smugglers, too, stand ready to exploit any substantial differential between the monopoly price charged the rich and the competitive market price charged the poor. Split markets with large price differentials thus generate unfairness as smugglers and selfish affluent patients benefit at the expense of honest affluent patients and innovators. More to the point, 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 undertake expensive R&D efforts in the first place. To avoid all these problems with large price differentials, it is best then to level pharmaceutical prices in the opposite direction: instead of unjustly imposing monopoly prices also on the poor (which effectively excludes most of them from advanced medicines), 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 symptom relief.

Because pharmaceutical R&D is urgently needed, loss of funding from monopoly patents must be replaced somehow – with public funds – to ensure a reliable flow long-term. As we will see, 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.

Mechanisms of public financing are usually categorized under the labels

of “push” and “pull”. A push program selects and funds some particular innovator — a pharmaceutical company, perhaps, or a university or a national health agency — to undertake a specific research effort. The intent here is that, with adequate funding, the selected innovator will develop the desired innovation, which can then be made freely available for production by competing pharmaceutical manufacturers so as to ensure wide availability at competitive market prices.

A pull program, by contrast, is addressed to many potential innovators, promising to reward whoever is first to achieve a valued innovation. Pull programs have two interrelated advantages over push programs: they avoid paying for failed research efforts and they generate strong financial incentives for innovators to work hard toward early success. The flip side of these advantages is that, in order to elicit such a serious research effort, the reward must be large enough to compensate for the risk of failure. This risk is twofold, as a research effort may fail either because the sought medicine proves elusive or because some competing innovator succeeds first. Potential innovators have incentives to try to develop a new medicine only if the reward for success, discounted by the probability of failure, is substantially greater than the expected cost of the R&D effort. In these respects, a pull program is similar to the current patent regime.

Despite this extra cost, pull programs can nevertheless be more effective than push programs, for three reasons: push programs are more likely to fail because they get only one rather than several competing innovators to work on the problem.<sup>23</sup> Push programs are more likely to fail because the innovator is chosen on the basis of some outsider’s confidence in it whereas in pull programs each innovator’s decision to try is based on *its own*, more competent and better motivated assessment of its capacities. Push programs are more likely to fail because the chosen innovator has much weaker incentives to work hard and cost-effectively toward early success. This higher probability of failure is compounded by the fact that such failures are paid for — in contrast to pull programs, which pay nothing for failed efforts. Given this contrast, pull programs are more easily sustainable, politically, in the long run.

Most prominent among pull programs are prize competitions that promise a reward to the innovator who is first able to produce a medicine that meets certain specifications. This reward can be specified as some monetary amount or as an APC or AMC (note 11). Such rewards have been described with considerable ingenuity.<sup>24</sup> They clearly can be a valuable complement to existing patent rewards and have the potential of stimulating the development of medicines for currently neglected diseases.

Nonetheless, such ad hoc prize competitions have four drawbacks. First, politicians, bureaucrats, or experts play a crucial role by deciding which diseases

should be researched, how the sought remedy should be specified, and how large a reward should be promised for a remedy meeting these specifications. Determining the direction research will take, these decisions are likely to be associated with substantial inefficiencies due to incompetence, corruption, gaming, and lobbying by companies and patient groups. Ideally, the relevant planners should aim to stimulate the most cost-effective innovations. But their own incentives to make this aim paramount are weak. And their information about the cost of specific research efforts to innovators is likely to be of poor quality, as potential innovators have reason to exaggerate both the costs and the potential utility of their efforts.<sup>25</sup> Given weak incentives and poor information, the planners' design of prize competitions would likely be seriously suboptimal.

The second problem arises from the fact that ad hoc rewards involve excessive specificity. Each reward must define a precise finish line, specifying at least what disease the medicine must attack, how effective it must minimally be (magnitude and duration of the improvement, percentage of patients), how bad its side effects may be (severity and frequency), and how convenient the medicine must minimally be (stability at various temperatures, frequency and mode of intake). Such specificity is problematic because it presupposes the very knowledge whose acquisition is yet to be encouraged. Since the sponsors lack this knowledge ahead of time, their specification is likely to be seriously suboptimal even if they are single-mindedly devoted to the goal of improving public health. Such suboptimality can take two forms. The specification may be overly demanding in at least one dimension, with the result that innovators give up the effort even though something close to the sought solution is within their reach. And the specification may be insufficiently demanding in some dimension(s), with the result that innovators, to save time and expense, deliver products that are just barely good enough to win the prize even when they could have done much better at little extra cost.<sup>26</sup>

The third disadvantage of ad hoc rewards is that the funding they depend on is likely to be haphazard and case-by-case. This is so because arbitrary factors and political contingencies will invariably enter into the choice of specific diseases and types of intervention around which prize competitions are organized. It is also likely that overall fund allocations will be erratic: when encountering budget problems, governments will tend to skip or to postpone planned reward competitions, and the conduct of other sponsors is also likely to be unduly influenced by extraneous factors (e.g., by their public-relations needs or by how much money they must spend in the current year to retain their tax-deductible status).

A fourth serious defect of ad hoc rewards is that they fail to address the "last-mile" problem, which is especially severe in the context of currently

neglected diseases that mostly affect the poor. The fact that a new vital medicine is available in large quantities, or can be produced very cheaply by generic producers, does not yet give poor populations real access to it. The reward pulls innovators to the invention of a new safe and effective medicine or even to its production in large quantities. But it does not pull this medicine the rest of the way to the patients who need it. It may seem that AMC's can get around this problem by making the reward conditional on the innovator finding willing buyers. But I am skeptical. If — as in one of Michael Kremer's numerical examples — a \$14 subsidy (up to 200 million doses) is promised for each dose the innovator can sell for \$1 or more, then the innovator has powerful incentives to induce or entice or bribe buyers regardless of how they intend to dispose of the medicine. If it must be used, as a condition of the subsidy, it may well be prescribed to patients irrespective of whether they need it or not.

## Solution

The basic idea for solving all these problems now lies open before us: pharmaceutical innovation should be encouraged through publicly funded rewards that are tied to actual health impact. This incentive should be specified in general terms, as a promise to reward *any* new medicine that works, in proportion to how well it works. The combination of these two elements has been described as creating a new, *comprehensive* AMC.<sup>27</sup>

An important third element of the solution is that the funding mechanism should be global (rather than national) in scope. The reasons that make the reform compelling in any one country or region make it compelling everywhere. Moreover, global scope avoids the problems associated with large price differentials. And global scope also brings huge efficiency gains by diluting the cost of the scheme without diluting its benefits. No matter how many beneficiaries we may add, the cost of achieving an innovation remains the same even while its aggregate benefit increases with the number of beneficiaries.<sup>28</sup> Pharmaceutical innovation is therefore best encouraged by promising to reward any safe and effective new medicine in proportion to its *global* health impact. Such a promise constitutes an AMC that is *fully* comprehensive: by including not merely all diseases but also all patients.

As all human beings are included in the benefits of pharmaceutical innovation, so its cost can be dispersed worldwide through an international agreement that reinforces the commitment of individual countries to the scheme. The agreement might create a *Health Impact Fund* (HIF) that offers a reward for any new medicine based on its health impact during its first decade or so.<sup>29</sup> To receive this reward, the innovator must make a concession affecting its price. This concession may be specified in two ways or as a disjunction of both. The

innovator might be required permanently to waive claims to market exclusivity on a medicine worldwide, enabling generic competition that would drive the medicine's price down to near marginal cost of production.<sup>30</sup> Or the innovator might be required, during a specified reward period, to turn over all revenues worldwide from the sale of its medicine, inducing the innovator to lower the price of the medicine to the point where the marginal health-impact reward from selling additional units just equals the marginal cost of producing such units. Either way, innovators would gain for each of their new medicines the option of forgoing monopoly rewards in favor of an alternative path that would provide ample rewards for the development of a new high-impact medicine without excluding the poor from its use.

To provide stable incentives, member states must guarantee funding some 15 years into the future to assure pharmaceutical innovators that, if they fund expensive clinical trials now, they can claim a full decade of health-impact rewards upon market approval. This guarantee might feature fixed annual pools to be shared among registered medicines in proportion to their respective health impacts or it might feature a fixed monetary amount per QALY.<sup>31</sup> The former solution makes the cost of the HIF predictable and may therefore be more attractive to governments. The latter solution makes the reward per QALY predictable and would therefore be more attractive to potential innovators. A simple compromise would fix each annual reward pool in proportion to the square root of the QALYs gained by all registered medicines that year, subject to a \$/QALY ceiling. For example, in its start-up phase the Health Impact Fund might promise annually to reward the health impact of each registered medicine at \$1000 per QALY if the health impact of all registered medicines is at or below the limit of 4 million QALYs. If the total health impact is above 4 million QALYs in any year, then the HIF promises to pay out more than \$4 billion but at a reduced reward rate per QALY. If the health impact of all registered medicines is 6.25 million QALYs in some given year, for instance, then governments face an increased payment of \$5 billion and innovators face a decreased reward rate of \$800 per QALY (the contribution of governments is increased by a factor of 1.25 and the reward for registered medicines is reduced by the same factor).

This kind of funding mechanism has important advantages. It achieves reasonable predictability for both governments and pharmaceutical innovators. It puts pharmaceutical innovators in a competitive position, inducing them to check one another's activities and health impact claims (if one company illicitly inflates its measured health impact, then other companies are short-changed through a reduced \$/QALY rate). It establishes an observable, market-based \$/QALY rate in pharmaceutical innovation. And it is scalable, allowing governments to scale up the HIF if it proves successful (downscaling is

constrained by the 15-year guarantee). Such scaling-up could take three forms: when governments find that even the maximum per-QALY rate of \$1000 elicits little innovation, they can raise this ceiling. They can also increase (beyond the initial 4 million QALYs) the limit to which this maximum rate holds. And they can reduce the steepness of the drop in the \$/QALY rate beyond this limit. Any such scaling-up can be financed through an increased commitment by the member states and/or through the accession of new members.

The establishment and scaling-up of the HIF would be facilitated by a rule that divides the cost of the HIF in proportion to the member states' respective gross national incomes (GNIs). Thus, if one member state's GNI is 3.7 times that of another, than the contribution assigned to the former will be 3.7 times that assigned to the latter. Such rigidity has three main advantages. First, the contributions of the various countries are automatically adjusted in a way that tracks their shifting fortunes — fast-growing countries automatically assume a larger share while countries in recession (declining GNI) find their burden alleviated. Second, such rigidity pre-empts protracted struggles over contribution proportions such as have marred the United Nations. Third, rigidity assures each country that any extra cost it agrees to bear by supporting an increase in the contribution schedule, say, is matched precisely by a corresponding increase in the contributions of all other member states. Getting a state to agree to commit an extra \$20 million is much easier if this agreement expands available rewards for pharmaceutical research by a much larger amount than if (as in conventional governmental research allocations) it adds merely \$20 million to the available funds.

If all countries of the world were to agree to join the effort, each would contribute less than 0.008 percent of its gross national income for the first 4 million QALYs. As citizens, we would all pay an additional 0.008 percent of our gross income in taxes (\$1 for every \$12,500 in gross income) and, by agreeing to do so, gain the equivalent of 4 million years of healthy life against the GBD. If countries representing only half the sum of GNIs were willing to participate, their citizens would contribute 0.016 percent of their gross incomes for the first 4 million QALYs — still a trivial amount relative to its impact and mitigated, of course, by the much greater affordability of HIF-registered medicines.

The solution is then to create — parallel to the existing patent regime — a Health Impact Fund that gives pharmaceutical innovators a standing option to forgo exploitation of their monopoly powers on any medicine worldwide in exchange for a guaranteed payment stream proportioned to this medicine's impact on the GBD. Let us recapitulate how this parallel track would provide a full systemic solution to the seven problems described at the outset.

**Diseases concentrated among the poor**, insofar as they substantially aggravate the GBD, would no longer be neglected. In fact, the more

destructive ones among them would come to present some of the most lucrative R&D opportunities for biotechnology and pharmaceutical companies. This would happen without undermining the profit opportunities such companies now enjoy.

**Bias toward symptom relief** would be absent from HIF-encouraged R&D. The HIF assesses each registered medicine's health impact in terms of how its use reduces mortality and morbidity worldwide — without regard to whether it achieves this reduction through cure, symptom relief, or prevention. This would guide firms to deliberate about potential HIF-track research projects in a way that is also optimal for global public health — namely in terms of the expected global health impact of the new medicine relative to the cost of developing it. The profitability of research projects would be aligned with their cost effectiveness in terms of global public health.

**High prices** would not exist for HIF-registered medicines, and innovators would typically not even wish for a higher price on their HIF-registered medicines. The reason is that a higher price would greatly reduce a drug's health impact rewards by impeding access to this drug by the very poor who make up about half the human population. On the HIF track, health benefits to the poorest of patients count equally with health benefits to the richest.

**Wastefulness** would be dramatically lower for HIF-registered medicines. There would be no deadweight losses from high mark-ups. There would be little costly litigation as innovators would welcome generic competitors who, by increasing access to the medicine, would boost the innovator's health impact reward. Given this situation, innovators might often not even bother to obtain, police and defend patents in many national jurisdictions. To be eligible for rewards proportioned to the global health impact of a new medicine, an innovator would need to show *only once* that it has a patentable product.

**Counterfeiting** of HIF-registered medicines would be much less attractive: with the genuine item available near marginal cost of production, much less profit can be made from producing and selling fakes.

**Excessive marketing** would also be much reduced for HIF-registered medicines. Because each innovator is rewarded for the health impact of its addition to the medical arsenal, innovators get no reward for switching patients over to a new drug that is no better than its predecessor and would consequently never register it with the HIF. Innovators would have incentives to urge a HIF-registered drug upon doctors and patients only insofar as such marketing results in measurable therapeutic benefits for which the innovator would then be rewarded.

**The last-mile problem** would be mitigated because each HIF-rewarded innovator would have incentives to ensure that patients are fully instructed and properly provisioned so that they make optimal use (dosage, compliance,

etc.) of its medicines, which will then, through wide and effective deployment, have their optimal public-health impact. Rather than ignore poor countries as unlucrative markets, pharmaceutical companies would, moreover, have incentives to work together toward improving the health systems of these countries in order to enhance the impact of their HIF-registered medicines there.

## Conclusion

This essay describes and justifies a complement to the existing monopoly-patent regime that would generate a flow of pharmaceutical innovation without depriving the poor of their freedom to buy new medicines at competitive market prices. In response one might ask why the Health Impact Fund here described should be confined to new medicines. There are other means for reducing the GBD, such as access to safe drinking water, adequate nutrition, clean sanitation, proper hygiene, protections (such as mosquito nets) against disease-carrying animals, off-patent medicines, and many more. Why reward only new pharmaceutical remedies when there are alternative, perhaps more cost-effective ways of averting the same diseases?

A partial answer is that the 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 how this drug affects the evolution of mortality and morbidity attributable to its target disease (the disease for which it is indicated). This impact 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, which is strongly affected by the extent to which doctors and nurses are locally available, know about the medicine, have it on hand, prescribe it, ensure that patients have access to it in the best dosage and in sufficient quantity, and instruct patients in its proper use.

The answer I have given does not fully overcome the objection. There are diseases — simple diarrhea, for instance — against which new medicines would be of limited help if any. Why should not efforts to reduce such diseases by securing access to off-patent medicines, to clean drinking water or to sanitation be funded insofar as they are no less cost-effective than the Health Impact Fund? I have no objection to such an extension of the reward scheme I have sketched. We can think of this scheme as the 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 the central module which will provide a useful paradigm for possible extensions and an impetus for further reform.

But why start with *this* module, centering around new medicines? Would the money not do more to protect the health of poor populations if it were spent on a global program of universal access to clean water or healthy nutrition? Perhaps it would. But let us not disregard the political realities. Bitter experience over many decades has shown that the world's governments are not prepared to spend tens of billions of dollars on clean water or nutritious food supplements. The provision of such basic goods is thought to deserve a few millions here and there, but certainly not tens of billions. The idea of spending such sums on supporting domestic corporations, by contrast, is entirely familiar and commonplace — in fact, the affluent countries are spending *hundreds* of billions *each year* on export credits and subsidies, which aggravate severe poverty abroad, in the agricultural sector alone. A politically realistic way forward might then tie together the two objectives of protecting the poor and providing business opportunities to large corporations. The HIF I have sketched is meant to fit this description. There may be more cost-effective schemes for protecting the poor. But such alternative schemes are useless nonetheless if they cannot attract the funds they plan to spend. Aligning with the powerful interests of the pharmaceutical and biotechnology industries, the HIF has better prospects for success.

I am aware that I have not had the space to discuss fully how the proposed HIF should best be designed. This is evidently a highly complex question. Addressing it adequately would require specification of the reward mechanism: definition of an appropriate metric for the GBD, rules for allocating the GBD among the various diseases, ways of collecting sufficient data to assess ex post the global burden each disease imposes and to make plausible baseline projections some years into the future, rules for allocating specific disease burden reductions among contributing registered innovators, specific rules for determining a monetary reward for a given set of GBD reductions, adequate mechanisms for curbing corruption and gaming, and special rules for incremental innovations and for the phase-in period. Another aspect of the design concerns the agency administering the reward mechanism and the arbitration procedures for settling conflicts about the interpretation and application of the rules. A third design aspect concerns the treaty rules for funding the scheme along with the penalties for free-riding by countries that seek to take advantage of HIF-supported innovation without sharing its cost. We have an interdisciplinary and international team — supported by the Australian Research Council, the BUPA Foundation and the European Commission — hard at work on detailing workable solutions to these challenges. Our work is documented, with some time lag, at <[www.IncentivesForGlobalHealth.org](http://www.IncentivesForGlobalHealth.org)>.

Let me close with two more general lessons this essay supports. One

concerns the tragicomical disputes over globalization. The friends of WTO globalization spend billions to have the media reiterate the benefits of free markets and free enterprise. The opponents of WTO globalization mobilize millions of people to demonstrate against the damage free markets threaten to do to human values and well-being. In this unequal dispute, the reality of WTO globalization is overlooked by both sides — intentionally by the proponents, most often, and inadvertently by the opponents. The reality is that WTO globalization is opening markets where this serves important corporate interests in powerful countries, is preserving barriers to free exchange where this serves important corporate interests in powerful countries, and is shutting down free and open markets where this serves important corporate interests in powerful countries. The third type is exemplified by the case we have discussed, as large pharmaceutical corporations have won the right to use monopoly patents to block free trade in vital medicines worldwide. The second case is exemplified by the uneven fortunes of protectionism: while poor WTO members are forced to open their markets, wealthier members maintain their tariffs and anti-dumping duties as well as their huge export credits and subsidies to domestic producers. To be sure, these protectionist measures are often theoretically illegal under WTO rules. But less developed countries usually lack the resources to bring and win cases against the US or EU. Moreover, such a country has little to gain from winning as affluent members typically continue their Treaty contraventions even in the face of clear-cut WTO rulings, confident that the weaker member will prudently refrain from imposing the retaliatory measures such rulings may entitle them to and that these retaliatory measures would, in any case, not seriously hurt them.

The other more general lesson is about political change. There is much lament about how evil corporations are putting profits above people, above health, above animal welfare, above the environment. These laments are true, but usually misdirected. The *root* of the evil lies not in how corporations do business, but in how *we* regulate and incentivize them. If we structure markets so that corporations can earn billions by getting people to smoke, then corporations will work hard to get people to smoke. If we structure markets so that corporations can earn billions by getting people to stop smoking, then corporations will work hard to get people to stop smoking. Highlighting the moral responsibilities of corporations and their leaders is appropriate even if it makes little difference to what they do. But it may also detract from *our* responsibility as citizens to structure markets so as to encourage good corporate behavior. Having failed to do so, it is now *our* responsibility to devise politically realistic reforms, that is, reforms that the more powerful corporations and governments may well support or at least accept. This responsibility motivates

the reform effort I have described. We must restructure the existing global patent regime so that pharmaceutical innovators lose the financial stake in the proliferation of their target diseases and gain a financial stake in the elimination of these diseases. If we can thus redirect present incentives, then the immense powers of free enterprise will be marshaled *against* the devastating diseases that are now allowed to proliferate. If we manage to reorient pharmaceutical and biotechnology companies by aligning their profits with GBD reduction, these companies will be much more effective than the current assortment of ad hoc initiatives at defeating these diseases which bring so much misery and premature death to poor people everywhere. Working for this goal is politically realistic insofar as the envisioned structural reform is in the interest not only of the poor worldwide but also of the global pharmaceutical industry whose profitability it would enhance and whose tarnished image it would help to restore. These benefits come at very little cost because of the huge inefficiencies the reform reduces and because the benefits of intellectual property can be extended without cost.

## NOTES

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1. POGGE, T. Eradicating systemic poverty: brief for a global resources dividend. *Sur – International Journal on Human Rights*, São Paulo, v. 6, p. 136-158, 2007.
2. Ibid., note 27 and RONEY, M. The global millionaire boom. *Business Week*, 17 Oct. 2007. Available online at: <[www.businessweek.com/bwdaily/dnflash/content/oct2007/db20071017\\_916634.htm](http://www.businessweek.com/bwdaily/dnflash/content/oct2007/db20071017_916634.htm)>. Accessed on: 18 April 2008.
3. DAVIES, J.; SANDSTROM, S.; SHORROCKS, A. and WOLFF, E. *The world distribution of household wealth*. Helsinki: UNU-WIDER, 2006, Appendix 1, Table 10a; and KROLL, L. and FASS, A. The world's billionaires. *Forbes*, New York, 3 Aug. 2007. Available online at: <[www.forbes.com/2007/03/07/billionaires-worlds-richest\\_07billionaires\\_cz\\_lk\\_af\\_0308billie\\_land.html](http://www.forbes.com/2007/03/07/billionaires-worlds-richest_07billionaires_cz_lk_af_0308billie_land.html)>. Accessed on: 18 April 2008.
4. Over the 1984-2004 globalization period, household final consumption expenditure per capita (in constant dollars) rose 56.3% in the high-income OECD countries. During the same period, real (inflation and purchasing-power adjusted) consumption expenditure reportedly rose 48.62% at the median, 33.72% at the 15<sup>th</sup> percentile, 31.92% at the 7<sup>th</sup> percentile, 22.87% at the 2<sup>nd</sup> percentile, and 9.64% at the 1<sup>st</sup> percentile. See Table 6 in POGGE, T. Growth and inequality: understanding recent trends and political choices. *Dissent*, New York, v. 55, Issue 1, 2008, p. 82-93. Available online at: <[www.dissentmagazine.org/article/?article=990](http://www.dissentmagazine.org/article/?article=990)>. Accessed on: 18 April 2008. See also MILANOVIC, B. *Worlds apart: measuring international and global inequality*. Princeton: Princeton University Press, 240 p., 2005, p. 108-111.
5. The 1979 data are from <<http://62.237.131.23/wiid/wiid.htm>>, line 4664. Accessed on: 18 April 2008. And from LEONHARDT, D. Larry Summers's evolution. *New York Times Magazine*, 10 June

2007. Available online at: <[www.nytimes.com/2007/06/10/magazine/10wwIn-summers-t.html?ref=magazine](http://www.nytimes.com/2007/06/10/magazine/10wwIn-summers-t.html?ref=magazine)>. Accessed on: 18 April 2008. The 2005 data are from RONEY, M. The global millionaire boom, op. cit..

6. The 1990 data are from Table 1 of REDDY, S. and MINOIU, C. *Chinese poverty: assessing the impact of alternative assumptions*. New York: Institute for Social, Economical Research and Policy/ Columbia University, p. 1-35, 2007. Available online at: <[www.socialanalysis.org](http://www.socialanalysis.org)>. Accessed on: 18 April 2008. The 2004 data are from the World Bank's World Development Indicators dataset, which is available to subscribers only. Accessed on: 18 April 2008.

7. See <<http://62.237.131.23/wiid/wiid.htm>>, line 476 (2004). Accessed on: 18 April 2008.

8. POGGE, T. *World poverty and human rights: cosmopolitan responsibilities and reforms*. Cambridge: Polity Press, second edition, 2008, chs. 6-8.

9. This calculation assumes constant nominal profit each year. In reality, annual profit may rise (e.g. through population growth) or fall (through reduced incidence of the disease or through competition from "me-too" drugs developed by competing firms).

10. Announced in 2003, this joint WHO/UNAIDS program was meant to provide, by 2005, anti-retroviral treatment to 3 million (out of what were then estimated to be 40.3 million) AIDS patients in the less developed countries. In fact, the number of patients receiving such treatment increased by only 0.9 million to reach 1.3 million by the end of 2005. See WHO, *Evaluation of WHO's contribution to "3 by 5"*. Geneva: WHO, 2006. Available online at: <[www.who.int/hiv/topics/me/3by5%20Evaluation.pdf](http://www.who.int/hiv/topics/me/3by5%20Evaluation.pdf)>. Accessed on: 18 April 2008.

11. A prize is a specific reward offered for the development of a new medicine that meets certain specifications. It can be in the form of a cash payment or in some other form, for instance the extension of a patent on another medicine that is in high demand by affluent patients. An advance purchase commitment (APC) is a promise to buy, at a pre-set and lucrative price, a certain large number of doses of a new medicine that meets certain specifications. An advance market commitment (AMC) is a promise to subsidize the sale of a certain large number of doses of a new medicine that meets certain specifications. The only AMC issued thus far — funded by Italy, the UK, Canada, Russia, Norway, and the Gates Foundation — is for vaccines against pneumococcal disease, a major cause of pneumonia and meningitis among the poor. News reports suggest that it is designed to serve pharmaceutical industry interests first and foremost. See, for example, MILLER, J. Vaccines for Africa 'face 700% mark-up'. *The Independent*, 18 Nov. 2007. Available online at: <[news.independent.co.uk/health/article3172164.ece](http://news.independent.co.uk/health/article3172164.ece)>. Accessed on: 18 April 2008.

12. In Thailand, Sanofi-Aventis sold its cardiovascular disease medicine Plavix for 70 baht (\$2.20) per pill, over 60 times the price at which the Indian generic firm Emcure agreed to deliver the same medicine (clopidogrel). See OXFAM. *Investing for life*. Oxfam Briefing Paper, Nov. 2007, p. 20. Available online at: <[www.oxfam.org/en/files/bp109\\_investing\\_for\\_life\\_0711.pdf/download](http://www.oxfam.org/en/files/bp109_investing_for_life_0711.pdf/download)>. Accessed on: 18 April 2008.

13. See SELGELID, M. Ethics and drug resistance. *Bioethics*, Johannesburg, v. 21, n. 4, p. 218-29, May 2007.

14. Personal communication from Aidan Hollis, based on his rough calculation. See also HOLLIS, A. *An efficient reward system for pharmaceutical innovation* (working paper). Calgary: University

of Calgary, 2005, p. 8. Available online at: <[www.patent2.org/elibrary.html](http://www.patent2.org/elibrary.html)>. Accessed on: 18 April 2008. Hollis there quantifies the deadweight loss in the region “of \$5 billion – \$20 billion annually for the US. Globally the deadweight loss is certain to be many times this figure, because in many markets drug insurance is unavailable and so consumers are more price-sensitive”.

15. See the Special issue on disease mongering. MOYNIHAN, R. and HENRY, D. (ed.). *PLoS Medicine*, Cambridge, United Kingdom, v. 3, issue 4, p. 425-465, 2006. Available online at: <[collections.plos.org/plosmedicine/diseasemongering-2006.php](http://collections.plos.org/plosmedicine/diseasemongering-2006.php)>. Accessed on: 18 April 2008.

16. The TRIPS Agreement is Annex 1C of the Marrakesh Agreement Establishing the World Trade Organization, signed in Marrakesh, Morocco on 15 Apr. 1994. Its full text is available online at: <[www.wto.org/english/tratop\\_e/trips\\_e/t\\_agm0\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/t_agm0_e.htm)>. Accessed on: 18 April 2008. Relevant are Articles 8(1) and 27(2). The full text of the Doha Declaration is available online at: <[www.who.int/medicines/areas/policy/tripshealth.pdf](http://www.who.int/medicines/areas/policy/tripshealth.pdf)>. Accessed on: 18 April 2008. Most relevant are Articles 4-6.

17. To be sure, to benefit many, the intellectual achievement must typically be physically encoded in multiple copies: in books, CDs, seeds, DNA molecule tokens, pills, or vaccines. Such physical instantiations of intellectual creations and discoveries do have a cost that rises — typically at a decreasing rate — as additional copies are made. But such physical reproduction is separable from, and adds nothing to the cost of, the creative intellectual labors. The creative intellectual ingredient into physical reproduction is entirely cost-free at the margin.

18. NOZICK, R. *Anarchy, state and utopia*. New York: Basic Books, 384 p., 1974, p. 181.

19. The most pertinent passages are LOCKE, J. An essay concerning the true original, extent, and end of civil government [1689]. In: LASLETT, P. (org.). *Two treatises of government*. Cambridge: Cambridge University Press, 1960, §27 and §33; and NOZICK, R. *Anarchy, state, and utopia*, op. cit., p. 181-182. Nozick approves of patents but, as I show in the text, this endorsement is inconsistent with the basis Nozick offers for it.

20. In this essay, I am not separately addressing utilitarian arguments for a global monopoly-patent regime. But it is obvious how they are bound to fail: even if funding pharmaceutical innovation in a way that includes the poor is less convenient for the affluent than the existing globalized monopoly-patent regime, this inconvenience is vastly outweighed by all the sickness and premature deaths that the present regime is adding to the burdens of poverty.

21. This injustice is independent of, and additional to, the great national and international injustices that keep half of humankind trapped in severe and avoidable poverty.

22. Before 2005, Indian law allowed only patents on processes, none on products. As a result, India's thriving generic pharmaceuticals industry, inventing new processes for manufacturing known medicines patented elsewhere, cheaply supplied such medicines for poor patients in India and throughout the world's poor regions. “But when India signed the World Trade Organization's agreement on intellectual property in 1994, it was required to institute patents on products by Jan. 1, 2005. These rules have little to do with free trade and more to do with the lobbying power of the American and European pharmaceutical industries. India's government has issued rules that will effectively end the copycat industry for newer drugs. For the world's poor, this will be a double hit — cutting off the supply of affordable medicines and removing the generic competition that drives down the cost of brand-name drugs.” EDITORIAL. India's choice. *The New York Times*, 18 Jan. 2005. Available online at:

<[select.nytimes.com/gst/abstract.html?res=F10610F8395C0C7B8DDDA80894DD404482](http://select.nytimes.com/gst/abstract.html?res=F10610F8395C0C7B8DDDA80894DD404482)>.  
Accessed on: 18 April 2008.

23. A push program might assign the same task to two or three innovators. But this would double or triple the cost and thereby dramatically erode the cost advantage over its pull-program alternative.

24. See especially KREMER, M. and GLENNERSTER, R. *Strong medicine: creating incentives for pharmaceutical research on neglected diseases*. Princeton NJ: Princeton University Press, 2004.

25. This informational deficit — though not the other problems with prizes — can be overcome through a tender system: The planners would publish the specifics of the medicine they wish to have invented and then invite companies and other capable agencies to enter competing “bids”, specifying the prize each would expect for producing a qualifying medicine as well as a deadline and a penalty for delays. The planners could then select the organization whose bid seems most attractive overall.

26. For an excellent discussion, see HOLLIS, A. *Incentive mechanisms for innovation*. Calgary: IAPR Technical Paper-University of Calgary, 43 p., 2007, p. 15-16. Available online at: <[www.iapr.ca/iapr/files/iapr/iapr-tp-07005\\_0.pdf](http://www.iapr.ca/iapr/files/iapr/iapr-tp-07005_0.pdf)>. Accessed on: 18 april 2008.

27. HOLLIS, A. *A comprehensive advance market commitment: a useful supplement to the patent system?* (working paper). Calgary: University of Calgary, 2007. Available online at: <[www.patent2.org/elibrary.html](http://www.patent2.org/elibrary.html)>. Accessed on: 18 April 2008.

28. In the case of medicines targeting communicable diseases, this benefit will increase super-proportionally: Each user of such a medicine benefits from others using it as well, because wide use can decimate or even eradicate the target disease and thereby reduce the probability that this disease will adapt and rebound with a drug-resistant strain (see note 13).

29. This corresponds roughly to the effective patent life of 20-year pharmaceutical patents, which are filed many years before market clearance.

30. See POGGE, T. *World poverty*, op. cit., ch. 9.

31. The QALY or quality-adjusted life year is a common measure of gains against the mortality and morbidity that constitute the GBD. It can be refined in various ways which I lack the space to discuss here. Basically, one QALY is an additional year of healthy life or a longer additional period of impaired life (e.g., 1.25 additional years with a 20% impairment of age-specific functioning).

## RESUMO

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Ao estabelecer altos preços para medicamentos avançados que se encontram fora do alcance de pacientes pobres e estimular a negligência de doenças concentradas nas populações mais pobres, o acordo TRIPS produz em escala maciça doenças e mortes evitáveis. Tal injustiça pode ser evitada através de um Fundo de Impacto sobre a Saúde Global (Health Impact Fund) que oferece àqueles que detêm a patente dos medicamentos a opção de oferecer os medicamentos a preço de custo em troca de uma recompensa monetária anual baseada no impacto deste medicamento na saúde global.

### PALAVRAS-CHAVE

Compromisso antecipado de mercado – Doença – Fundo de Impacto sobre a Saúde – Incentivos – Justiça – Medicamentos – Monopólio – Patentes – Pobreza – Bem público – Pesquisa – Direitos – TRIPS

## RESUMEN

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El Acuerdo ADPIC/TRIPS, al imponer unos precios sobre los medicamentos avanzados más allá del alcance de los pobres y al fomentar la ignorancia de las enfermedades que más les afectan, produce muertes y enfermedades evitables a una escala descomunal. Esta injusticia puede ser remediada a través de un Fondo de Impacto sobre la Salud que otorga a los propietarios de patentes la opción de establecer los precios de cualquier nuevo medicamento a nivel del costo a cambio de una recompensa monetaria anual en función del impacto de este medicamento sobre la salud global.

### PALABRAS CLAVES

Compromiso Anticipado de Comercialización– Enfermedad – Fondo de Impacto sobre la Salud – Incentivos – Justicia – Medicina – Monopolio – Patente – Pobreza – Bien público – Investigación – Derechos – ADPIC/TRIPS