Intellectual Property Rights and Access to Essential Medicines*

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0 Introduction

Some 18 million human beings avoidably die each year from diseases we can prevent, cure, or treat. This is equivalent to 50,000 avoidable deaths per day, or one-third of all human deaths.¹ Hundreds of millions more suffer grievously from these diseases.² The lives of additional hundreds of millions are shattered by severe illnesses or premature deaths in their families. These diseases also put great strains on the economies of many poor countries, communities, and families, thereby perpetuating their poverty, which in turn contributes to their members’ ill health.

This huge incidence of mortality and morbidity is not randomly distributed. For a variety of social reasons, people of color and children are heavily overrepresented among those suffering severe ill health³ — and, within these categories, women and girls in particular.⁴ The most significant causal factor determining this distribution is poverty: Nearly all of the avoidable mortality and morbidity occurs in poor countries and especially among their poorest inhabitants.⁵

There are different ways of attacking this huge global burden of disease (GBD) through institutional reforms. One approach, explored in chapters 5-8, focuses on the eradication of severe

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poverty. As we have seen, relatively minor and realistically attainable institutional reforms — causing a shift of no more than one percent in the global income distribution — would suffice to end severe poverty worldwide. The bottom half of the human population would still live on well under three percent of the global product. But they would be much better able to gain access to things that help the rest of us ward off ill health, such as adequate nutrition, safe drinking water, adequate clothing and shelter, basic sanitation, mosquito nets, and so on.

Another way of addressing the huge incidence of avoidable mortality and morbidity is through ensuring improved access to medical interventions — vaccines, cures, and treatments. The two ways of approaching the problem are complementary: Just as the eradication of severe poverty would greatly reduce the GBD, so reducing the GBD through improved access to essential medicines would greatly reduce severe poverty: by enhancing the ability of the poor to work, and to organize themselves, for their own economic advancement. Exemplifying the latter approach, this chapter outlines how one crucial obstacle to a dramatic reduction in the GBD can be removed.

The existing intellectual property regime for pharmaceuticals is morally deeply problematic. Long recognized among international health experts, this fact has come to be more widely understood in the wake of the AIDS crisis which pits the vital needs of poor patients against the need of pharmaceutical companies to recoup their investments in research and development. Still, this wider recognition does not easily translate into political reform. Some believe, like Winston Churchill about democracy, that the present system is the worst except for all the others. Others, friendlier to reform, disagree about what the flaws of the present system are exactly and have put forward a confusing array of alternative reform ideas.

We need a concrete and specific reform plan that is fully informed by the relevant facts and insights from science, statistics, medicine, public health, economics, law, and moral and political philosophy. This plan must be worked out to the point where it is ready for implementation and can serve as a clear focal point for policy makers, health-focused agencies and organizations, the media and the general public. To have a chance for implementation, such a plan must be politically feasible and realistic. To be feasible it must, once implemented, generate its own support from governments, pharmaceutical companies, and the general public (taking these three key constituencies as they would be under the reformed regime). To be politically realistic, the plan must possess moral and prudential appeal for governments, pharmaceutical companies, and the general public (taking these three constituencies as they are now, under the existing regime). A reform plan that is not incentive-compatible on both these levels will not succeed. One important implication is that we will reach our
common and imperative goal of universal access to essential medicines either in collaboration with the pharmaceutical industry or not at all.

This chapter sketches a concrete, feasible, and politically realistic plan for reforming current national and global rules so as to give the pharmaceutical industry stable and reliable financial incentives to address the severe health problems of the poor worldwide. If adopted, this plan would not add much to the overall cost of global health care spending. In fact, on a full 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 decision about whether and how to implement such a plan rests with national governments, and with their international organizations such as the WTO and WHO. But ultimately, these governments are accountable to the people they represent, who in turn bear ultimate responsibility for their decisions. It is a widely shared responsibility and an urgent task to explore and assess the more promising reform options toward reducing the vast disease burden produced and reproduced by current institutional arrangements.

1 The TRIPS Agreement and its aftermath

During the last 15 years, the United States and other affluent countries have worked hard and successfully to incorporate substantial and uniform protections of intellectual property rights into the fabric of the global trading system. This initiative included the Trade-Related Aspects of Intellectual Property Rights or TRIPS Agreement formulated in the so-called Uruguay Round that led up to the formation of the WTO. It was continued through a series of bilateral free-trade agreements including additional (“TRIPS-plus”) provisions that enable patent holders to extend, or “evergreen,” their monopolies well beyond the 20 years enshrined in the TRIPS Agreement and also discourage, impede, and delay the manufacture of generic medicines in many other ways — through provisions on data exclusivity, for instance, and through restrictions on and political pressures against the effective use of compulsory licenses.

Intellectual property rights can help ensure that creative works of music, film, art, poetry and prose are protected from unauthorized modification and that their authors receive royalties or licensing income from the reproduction of their work. Much more consequential than such copyrights are rights to software and technologies and especially monopoly patents over biological organisms
(such as the seeds of plants used for food), over medically useful molecules, or over pharmaceutical research tools needed to develop new medicines. Patents of these kinds are morally problematic insofar as they, directly or indirectly, impede access by the global poor to basic foodstuffs and essential medicines. The urgency of this concern manifests itself in the global incidence of malnutrition and disease.

It is a wonderful thing about the products of thought that their costs are 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. 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. And one may then be tempted to think that poor people, at least, should have access to this creative intellectual ingredient free of charge, that is, should pay only the market price for physical reproduction (for manufacturing additional copies to meet their demand).

Yet, the grand intellectual property rights initiative of recent years goes exactly in the opposite direction. Its driving idea is that benefits derived from most such intellectual achievements, by any person, anywhere, must be paid for, and that any unpaid-for benefit constitutes theft, piracy, counterfeiting, or worse. Even though the additional ride is entirely cost-free, none are to have a free ride — no matter how desperately poor they may be and no matter how desperately they may need it. Implementing this driving idea by awarding monopoly pricing powers greatly raises the price of commodities containing intellectual-property components — often by a factor of 10 to 30 in the case of pharmaceuticals.

There can be a rationale for so excluding people from a good that costs nothing at the margin. In some cases access to such a good is more valuable, or more appreciated, when others have no access to it. A powerful new software tool, for instance, may be of great value to an investment bank, but only so long as its rivals lack access to the same program. And a dashing handbag design may give great pride and pleasure to its wearers, but only so long as they are a small minority. In such cases, enforced exclusivity can make sense because extending access — though it adds nothing to the
labors of innovation — does impose a cost on those who would otherwise be exclusive beneficiaries of the innovation.

This rationale is absent in the case of pharmaceutical innovation where the externalities of extending access are positive on the whole. To be sure, there are respects in which we benefit when others fall ill, remain ill, or die prematurely. But, quite apart from their odiousness, these benefits are dwarfed by the costs, among which the resulting economic burdens and the dangers to public health are the most obvious. Even the wealthy benefit on the whole when the poor are given free access to a pharmaceutical innovation rather than excluded from it. We have reason to want dangerous diseases to be decimated or eradicated, like smallpox, rather than kept around, like AIDS, as a massive burden on the poor and threat to all. So why should we exclude the poor from the benefits of pharmaceutical innovation by insisting on the global enforcement of exorbitant rents for the owners of intellectual property?

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 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.11

What could possibly justify our blocking the supply of life-saving medicines from Indian manufacturers to the world’s poorest populations? In response to this challenge, one might assert a natural right of any inventor to control the use of his invention. But this assertion faces serious difficulties, four of which I now highlight.

One difficulty is that of explaining why such a natural right of inventors should have precisely the contours enshrined in the TRIPS/TRIPS-plus agreements and implementing national legislation: why should this natural right cover all and only the intellectual achievements that can now be legally protected by monopoly patents, copyrights, or trademarks? Why should this natural right have
exactly the breadth and duration now globalized under WTO auspices? There have been many
diverse national intellectual property regimes and one could imagine any of these, and many more,
instituted globally. Such regimes differ in how they strike a balance between the interests of
innovators and potential beneficiaries. Patents might have longer or shorter lives, there is much
leeway in fixing the conditions under (and terms on) which they may be infringed, and
differentiations in these and other respects might be made according to the character of the innovator,
of the innovation, of its user and of the use.

Another difficulty — especially relevant to patented seeds and pharmaceuticals — is that of
showing that this natural right of inventors is so weighty that even the right to life of poor people
(lacking food or medicine) must be curtailed to accommodate it, rather than the other way around.\textsuperscript{12}
It is also difficult to show that this natural right favors pharmaceutical firms as exclusive recipients of
intellectual property rights when their products rely so heavily on basic research conducted at
universities and public institutions with funds supplied by governments and tax-advantaged
foundations\textsuperscript{13} — not to speak of their broader reliance on the surrounding social infrastructure and
the preceding centuries of human intellectual exertions.

But let me here focus on the more fundamental difficulty of justifying any natural right of
innovators to control the use of their inventions at all. Even the most property-friendly accounts of
rights — those of right-wing libertarians — have trouble explaining how the innovative creation of a
physical object should earn the innovator property rights not merely in this object \textit{token} but in all
objects of its type. These accounts appeal to Locke’s view that a person who produces something out
of ingredients he legitimately owns comes to own the product along with an entitlement to veto
others’ use thereof. And these accounts take as axiomatic that such a person’s entitlement to the
products of his labor trumps the needs of others, no matter how desperate. Accordingly, Robert
Nozick insists that a medical researcher may withhold a medicine he invented even from those who
need it to survive. In endorsing this view, Nozick specifically appeals to the Lockean proviso: “A
medical researcher … does not worsen the situation of others by depriving them of whatever he has
appropriated. The others easily can possess the same materials he appropriated; the researcher’s
appropriation or purchase of chemicals didn’t make those chemicals scarce in a way so as to violate
the Lockean proviso.”\textsuperscript{14}

This line of thought provides no rationale for concluding that the medical researcher is
entitled to veto others’ replicating his activity with like chemical ingredients \textit{they} legitimately own.
To be sure, Nozick approves of patents. He writes that patents do not make other worse off than they
would have been without the patented invention, and he exempts from the reach of each patent those
who can prove that they made the same invention independently. But these judgments have no basis whatsoever in his theory. That an acquisition does not make others worse off is a necessary but insufficient condition for its validity. It goes no way toward explaining how someone can make himself owner of a type: how someone who combines stuff he legitimately owns can thereby acquire veto powers over what others can do with stuff they legitimately own. Suppose John discovers that he likes certain dishes better when he adds a little tree bark to them, and suppose he declares himself the owner of the type dishes with tree bark. As it happens, no one else likes tree bark in their dishes, so no one is made worse off by the veto powers John asserts. But even then, John’s natural-right claim remains unjustified: Why should he be entitled to veto other’s adding tree bark to their dishes? Nozick’s theory provides no support for such an entitlement.

In fact, Nozick’s theory provides a reason against such an entitlement in the more pertinent cases where the invention or discovery can be useful to others. To illustrate, let us change the foregoing example by replacing tree bark with mushrooms, whose addition makes many dishes taste better to most people. In such cases, Nozick’s theory militates against a natural right of John’s to declare himself owner of the dishes with mushrooms type, with veto powers over the production of such dishes. Doing this, John would be making others worse off. He would be partially expropriating them without their consent and without compensation. He would be doing this by unilaterally imposing a cumbersome condition to their exercise of their property rights: They must now refrain from adding their own mushrooms to their own dishes or pay John whatever fee he asks for the privilege of doing so or else prove that they came up with the idea of adding mushrooms independently of John. It is both absurd and unlibertarian to think that John has a natural right to such a unilateral imposition.

Applying all this to medicines, recall the condition Nozick attaches to the researcher’s right to keep the physical medicine he has synthesized to himself, or to sell it at an exorbitant price, even if many die as a result. The researcher has a right to do this, according to Nozick, because he is not thereby making others worse off, is not creating scarcity. However true this may be of the researcher Nozick discusses, who lays claim only to the medicine (token) he has synthesized out of his own chemicals, it is false of the researcher who lays claim to the type. This latter researcher is making others worse off by depriving them of the opportunity to invent the medicine without having to prove that they did so independently. And he is creating scarcity by claiming that only he can grant others access to certain uses of their property. What Nozick himself says in defense of the first researcher’s entitlement thus defeats the claimed entitlement of the second. Nozick’s argument not merely fails to support the latter’s claim but even requires that others be left free to replicate the latter’s invention.
researcher may keep his knowledge and medicine entirely to himself, even if many die as a result, and he may also sell his medicine only to those who contractually promise not to allow it to be analyzed or reproduced. But he cannot acquire veto powers over third parties who synthesize medicine of the same type on their own — even if they heard about his prior invention or found a sample of it lost or abandoned. Far from supporting intellectual property in particular types of medicine, libertarian and deontological accounts such as Nozick’s actually refute such property rights: Specific quantities of medicine (token) can be owned exclusively only because and insofar as such ownership leaves undisturbed the freedom of others to produce (if they can) medicine of the same type. Those who would appropriate a type of substance to themselves violate the Lockean proviso by not leaving enough and as good for others.

2 The argument from beneficial consequences

The difficulties of defending (legal) intellectual property rights by appeal to (moral) natural rights are so overwhelming that most defenders of the ongoing intellectual property initiative appeal instead to the beneficial consequences of protecting property rights in intellectual achievements: such legal rights incentivize intellectual innovation, or so we are told. The experience of recent years suggests that intellectual property rights in seeds and medicines inspire a great deal of copy-cat efforts and innovative gamesmanship — attempts to influence the formulation of the rules and attempts abusively to take advantage of the rules. Still, intellectual property rights do encourage research efforts that result in genuinely new seeds and pharmaceuticals. So the argument from beneficial consequences cannot be dismissed.

To assess this argument, we need to ask: how does the global intellectual property regime now taking shape affect the well-being of diverse human populations? In examining this question, it is crucial to avoid the false dichotomy that asks us either to accept this emerging regime or else to renounce all hope for innovation. A third possibility was exemplified in the recent past, when intellectual property rights were legally recognized in most affluent countries but not, or not to anything like the same extent, in most of the poorer ones. The existence of this third possibility has two implications. First, the consequence-based argument for the current regime cannot succeed by showing merely that this regime is preferable to the complete absence of intellectual property rights anywhere. Second, the consequence-based argument for the ongoing intellectual property initiative fails if the loss it brings for poor populations (by reducing their access to patented seeds and pharmaceuticals) is greater than the gain it brings to richer populations (by boosting corporate
income from monopoly patents and by accelerating the development of new seeds and pharmaceuticals). On any plausible accounting, which attaches no less weight to the well-being of poor people than to that of the affluent, the new global intellectual property regime is greatly inferior to its more differentiated predecessor.

To see this, consider the shift from the standpoint of the four main affected groups:

(i) potential innovators in the pharmaceutical and biotechnology industries with their shareholders and researchers,
(ii) affluent people as actual and potential patients,
(iii) generic manufacturers of pharmaceuticals with their shareholders and researchers;
(iv) poor people as actual and potential patients.

Pharmaceutical and biotechnology companies along with their shareholders and researchers benefit from the global enforcement of intellectual property rights in pharmaceuticals: They can now use the law to suppress the manufacture and delivery of generic versions of their patented medicines pretty much anywhere. By globally enforcing its monopoly in this way, a patent-owning firm can cut patients off from cheaper, unlicensed versions of its medicine, thereby increasing both the sales volume and the price of its licensed version.

For affluent patients and potential patients, the picture is mixed. On the one hand, they lose opportunities to buy cheaper unlicensed versions of the medicines they need. On the other hand, through strengthened incentives toward pharmaceutical innovation, they can look forward to more rapid pharmaceutical innovation resulting in a superior arsenal of medical interventions available to them. There is reason to believe that the ongoing intellectual property initiative, on balance, benefits this second group as well through stronger innovation incentives. A minority of older affluent patients compelled to switch from cheap generics to more expensive licensed versions of patented medicines may be net losers from having to shoulder a share of the cost of pharmaceutical innovation. But for the vast majority of affluent people — those who are either young (thus more affected by the pace of pharmaceutical innovation) or healthy (thus not currently in need of patented medicines) or anyway unwilling or unable to take advantage of generic versions of patented medicines — the advantage of stronger innovation incentives is likely to be decisive.

The global enforcement of monopoly patents is clearly a set-back for the generic drug producers and for their shareholders and researchers. They lose the opportunity to sell unlicensed versions of patented medicines to affluent patients eager to save money as well as to poor patients who simply cannot afford the much more expensive licensed version. But these companies can adapt
to their new regulatory environment and, especially in India, many are rapidly reorganizing themselves toward serving patients in wealthier countries by researching and developing innovative medicines for the ailments of the affluent.\textsuperscript{21}

Poor patients and potential patients are the fourth relevant group. The newly globalized patent regime effectively cuts them off from advanced essential medicines by rendering such medicines unaffordable to them and by massively diluting the capacity of national health systems, international development agencies, and non-governmental organizations to buy these medicines for them. Millions of deaths from AIDS and other treatable or curable diseases are due to the suppression of manufacture and trading of generic drugs. As those who cannot afford advanced medicines at prevailing monopoly prices greatly outnumber the affluent and also have much more at stake than the latter, it is evident that — on any honest accounting that gives no less weight to the interests of the poor than to that of the affluent — the recent tightening of the intellectual property regime must be judged socially harmful. For the sake of strengthening incentives toward pharmaceutical innovations that benefit themselves and their constituents, representatives of the world’s most affluent populations have destroyed the opportunities of much larger numbers of much poorer people (and of organizations working on their behalf) to purchase cheap medicines from willing suppliers at competitive market prices.

One could respond that, if tightened intellectual property rules accelerate pharmaceutical innovation, then the poor will also benefit eventually. The 20-year delay imposed upon them will remain constant relative to the access affluent people enjoy. But this delay will shrink relative to what the poor would have had under a continuation of the pre-TRIPS regime. Thus suppose that tightened intellectual property rules accelerate pharmaceutical innovation by 20%. If so, the next 100 years will bring as much pharmaceutical innovation as 120 years of continued pre-TRIPS would have brought. Despite the 20-year delay, the poor 120 years in the future will then be about as well off as they would have been if the pre-TRIPS regime had continued — and the poor further in the future will be better off than would otherwise have been the case.

This response ignores the fact that, by the time a patent expires, some drugs have lost much of their therapeutic value due to increasing resistance developed by the pathogen. The response is moreover difficult to articulate in the face of millions of people whose survival or health depends on access to these medicines \textit{now}. Yet, it contains a real insight that points us beyond the two regimes we have considered in this section: the emerging TRIPS/TRIPS-plus regime and its more differentiated predecessor: When pharmaceutical innovation is driven by paying patients, then there
is a trade-off between access by the poor to existing medicines and inclusion of their health problems on the pharmaceutical research agenda. The next section returns to this point.

But first let us ask: if the new regime is so much worse for the global poor, then why did they agree to it? Membership in the WTO is voluntary, after all, and the poor countries chose to sign up. And are they not more reliable and more legitimate judges of their own interests than we outsiders are?

To understand why this objection fails, one must bear three points in mind. First, in the negotiations that preceded the WTO Agreement and its subsequent modifications, the representatives of the poor countries were “hobbled by a lack of know-how. Many had little understanding of what they signed up to in the Uruguay Round.” Back then, poor-country representatives were facing some 28,000 pages of treaty text drafted in exclusive (“Green Room”) consultations among the most powerful countries and trading blocks. Most poor-country delegations could not possibly understand the full meaning and implications of the treaty they signed in hopes of greater access to the rich countries’ markets.

Second, most poor countries lacked the bargaining power needed to resist the imposition. All the Western free-trade rhetoric notwithstanding, the poor countries are compelled to pay dearly for access to our huge markets. Any poor country is required to open its own markets widely to the corporations and banks of the affluent countries and required also to commit itself to the costly enforcement of their intellectual property rights. The World Intellectual Property Organization (WIPO), a specialized agency of the United Nations, is charged with “helping” poor countries enforce intellectual property rights. The cost of such enforcement efforts cuts into government expenditures on basic social services: “implementing commitments to improve trade procedures and establish technical and intellectual-property standards can cost more than a year’s development budget for the poorest countries.” And the extraction of monopoly rents for foreign corporations also raises prices in poor countries, including prices charged for seeds and essential medicines. If deemed insufficiently aggressive in the enforcement of foreign intellectual property rights, such countries are singled out in the so-called 301 Reports of the US Trade Representative, where currently some 40 countries are held up for reprimand and exposed to actual or possible trade sanctions (www.ustr.gov). Poor countries deemed sufficiently aggressive in enforcing the extraction of monopoly rents for foreign corporations avoid trade sanctions. But even they get nothing like full access to the markets of the rich countries, which continue to be heavily protected through quotas, tariffs, anti-dumping duties, export credits, and huge subsidies to domestic producers. Such protectionist measures are most severe in precisely the areas — textiles, footwear, agricultural
products — where poor countries would otherwise be most competitive. Regularly lamented by top officials of the global trading system, such rich-country protectionism costs the poor countries around $1000 billion annually in lost export revenues.

The third point we need to bear in mind is that political power in the poor countries is typically very unevenly distributed. Even if an international treaty is disastrous for a country’s poor majority, signing up to this treaty as proposed by the affluent states may nonetheless be advantageous for this country’s political and economic elite. It may be advantageous to them by affording them export opportunities, by winning them diplomatic recognition and political support, by enhancing their access to weapons, by protecting their ability discreetly to transfer and maintain wealth abroad, and in many other ways. Consent by the ruling elite is not, then, a valid indicator of advantage to the general population. This point is made vivid when we look through the list of rulers who actually signed up their countries to the WTO Agreement. Among them we find Nigeria’s military dictator Sani Abacha, Myanmar’s SLORC junta (State Law and Order Restoration Council), Indonesia’s kleptocrat Suharto, Zimbabwe’s Robert Mugabe, Zaire’s Mobutu Sese Seko, and a host of less well-known tyrants of similar brutality and corruption. Even if the consent of these rulers was rational in reference to their own interests, it hardly follows that this consent was in the best interest of their oppressed subjects.

Reflections on this third point also speak to another popular defense of the new rules of the world economy. This defense points out that it is not unfair to hold people to rules that are disadvantageous to them if these people themselves have agreed to the rules beforehand. *Volenti non fit iniuria* — no injustice is being done to the willing. The problem with this defense is that, at best, it justifies the status quo only insofar as the consent of national populations can be inferred from the signatures of their rulers. But in countries like those just listed we cannot plausibly consider the population to have consented through its rulers. How can a tyrant’s success in subjecting a population to his rule by force of arms give him the right to consent on behalf of those he is oppressing? Does this success entitle us to count the ruler’s signature as the population’s consent? On any credible account of consent, the answer is no. We cannot invalidate the complaint of those now excluded from essential medicines by appealing to the prior consent of their ruler when this ruler himself lacks any moral standing to consent on their behalf. And even in cases where this ruler has some moral standing, his consent still cannot waive supposedly inalienable human rights of his subjects — including children, who constitute the majority of those affected — whom the rich countries’ intellectual property initiative is depriving of secure access to essential medicines.
But is it not an accepted principle that those exercising effective power in a country are entitled to act on behalf of its people? Yes, indeed, it is current international practice to recognize any person or group holding effective power in a country — regardless of how they acquired or exercise it — as entitled to sell the country’s resources and to dispose of the proceeds of such sales, to borrow in the country’s name and thereby to impose debt service obligations upon it, to sign treaties on the country’s behalf and thus to bind its present and future population, and to use state revenues to buy the means of internal repression. This practice of recognition is of great importance to us — mainly because we can gain legal title to the natural resources we need from anyone who happens to possess effective power. This practice is also well-liked among rulers, elites, and generals in the poor countries. Yet the effects of this accepted international practice on the world’s poor are devastating (cf. chs. 4 and 6): The practice enables even the most corrupt and illegitimate juntas or dictators to entrench themselves. Such rulers can violently repress the people’s efforts toward good governance with weapons they buy from abroad and pay for by selling the people’s resources to foreigners and by mortgaging the people’s future to foreign banks and governments. Greatly enhancing the rewards of de facto power, the practice also encourages coup attempts and civil wars, both of which often provoke opportunistic military interventions from neighboring countries. And in many (especially resource-rich) countries, these privileges make it all but impossible, even for democratically elected and well-intentioned leaders, to rein in the embezzlement of state revenues: any attempt to hold military officers to the law is fraught with danger, because these officers know well that a coup can restore and enhance their access to state funds which, after such a coup, would still be replenished through resource sales and still be exchangeable for the means of domestic repression. Far from being a defense against the charge that the newly globalized intellectual property regime is harming the global poor, the present practice of international recognition is a further example of such harming.

We have seen that, on any plausible accounting of social benefit, the rich countries’ intellectual property initiative goes in the wrong direction, foreseeably causing many additional premature deaths among the global poor by cutting them off from life-saving patented medicines. Although generic producers in poor countries could manufacture such medicines cheaply for use throughout the world’s poor regions, they are no longer permitted to do so; and these medicines are now available only at monopolistic prices, typically vastly higher than the (long-run) marginal cost of production.27

3 Toward a better way of stimulating research and development of essential medicines
Imagine for a moment that, in thinking about the design of a global scheme for pharmaceutical innovation, we gave no less weight to the interests of poor people than to those of the affluent. We would then want the intellectual achievements embedded in life-saving seeds and medicines to be freely available to poor populations. But such free availability, which was standard before TRIPS, leaves two big problems unaddressed. One problem is that the health systems of many poor countries are so undeveloped that they fail to afford poor people effective access even to essential medicines that are available cheaply or even (by donation) cost-free.

The other problem arises from the fact that poor populations face many serious health problems that are very rare among the affluent. These specific health problems are due to a variety of poverty-related factors: the global poor often lack access to minimally adequate nutrition, to clean water, to minimally adequate clothing, shelter, and sanitation, to sufficient sleep and rest, and to minimal health-related knowledge and advice. And little is done to control environmental hazards (such as disease-carrying insects, parasites, dangerous pollution, etc.) in regions inhabited by poor populations — even while such hazards have been successfully eradicated from affluent regions (e.g., South Florida) with similar climate and geography.

Although the specific health problems of the global poor constitute a very substantial portion of the GBD, they are predictably ignored under a regime that forces pharmaceutical inventor firms to recoup their research and development costs from paying patients. Such a regime foreseeably steers pharmaceutical research toward the health problems of the affluent and away from the much greater medical needs of the poor. Vastly more money and human ingenuity are invested toward finding remedies for hair loss and pimples, and toward inventing new disorders and ways to treat them, than toward developing effective medicines for diseases that are decimating the world’s poor. Even if common talk of the 10/90 gap is now an overstatement, the problem is certainly real: Malaria, pneumonia, diarrhoea, and tuberculosis, which together account for 21 percent of the GBD, receive 0.31 percent of all public and private funds devoted to health research. And diseases confined to the tropics tend to be the most neglected: Of the 1393 new drugs approved between 1975 and 1999, only 13 were specifically indicated for tropical diseases and, of these 13, five were byproducts of veterinary research and two had been commissioned by the military. An additional 3 drugs were indicated for tuberculosis. The next five years brought 163 new drugs of which 5 were for tropical diseases and none for tuberculosis. Tropical diseases and tuberculosis together account for 12% of the total disease burden.

Bringing new, safe and effective medications to market is hugely expensive on account of the research and development work involved as well as the elaborate testing and subsequent approval
In addition, a large proportion of such efforts fail at some stage of the process, as when a drug turns out to be unsafe or not effective enough, has bad side effects, or for some other reason is denied government approval. Those undertaking to develop a new medicine thus run a substantial risk of losing their entire investment.

Given such large investment costs and risks, very little innovative pharmaceutical research would take place in a free market system. The reason is that an innovator would bear the full cost of its failures, but would be unable to profit from its successes because competitors would copy or retro-engineer its invention (effectively free-riding on its effort) and then drive down the price close to the long-run marginal cost of production. This is a classic instance of market failure leading to a collectively irrational (Pareto-suboptimal) outcome in which medical innovation is undersupplied by the market.

The classic solution, globalized through the TRIPS regime, corrects this market failure through patent rules that grant inventor firms a temporary monopoly on their inventions, typically for 20 years from the time of filing a patent application. With competitors barred from copying and selling any newly invented drug during this period, the patent holder can sell it at the profit-maximizing monopoly price well above, and often very far above, its long-run marginal cost of production. In this way, the inventor firm can recoup its research and overhead expenses plus some of the cost of its other research efforts that failed to bear fruit.

This solution corrects one market failure (undersupply of medical innovation). But its monopoly feature creates another. During the patent’s duration, the profit-maximizing sale price of the new medicine will be far above its marginal cost of production. This large differential is socially harmful by causing a “deadweight loss”: It precludes mutually beneficial sales to potential buyers who are willing and able to pay more than the cost of production but not the much higher monopoly price. If modified rules could facilitate these potential transactions, then many patients would benefit — and so would the drug companies as they would book additional profitable sales and typically also, through economies of scale, reduce their unit cost of production.

The deadweight loss is common to all monopoly patents; they all impose sizable economic losses on the national and global economies. Essential medicines are a special case nonetheless in that here the deadweight losses are exceptionally deadly. However regrettable it may be that many poor people lack access to software, films, and music even when they are willing and able to pay for them at roughly the marginal cost of production — this loss is nothing compared to the millions of
premature deaths and the unimaginable suffering from diseases which arise from the present patent regime’s impeding mutually advantageous sales of essential medicines.

Let me inject here the clarification that by “essential medicines” I mean known medicines that are vital to human health and survival. The WHO maintains a list of essential drugs that it urges and expects all governments to make accessible to their populations. This list is constructed with an eye to cost-effectiveness. Many important but expensive drugs do not make the list because poor countries cannot reasonably be expected to provide them. It is appropriate in certain contexts to take as a given the existing patent regime and the high prices it engenders. But in the different context of this chapter, the importance of a medicine is defined independently of its price in order to focus sharply on the question how we can remove the obstacle of high prices that now impedes access to important medicines. This clarification should guard against the true and oft-repeated, but silly, objection that monopoly prices hardly ever impede access to essential drugs as listed by the WHO.

4 Differential pricing

There are two basic reform strategies for avoiding the second market failure associated with monopoly pricing powers: differential-pricing and public-good strategies. The differential-pricing strategy comes in different variants. One would involve a return to the period before TRIPS, when patent monopolies for advanced medicines were awarded and enforced in affluent countries but not in most of the poorer ones. Another variant would have inventor firms themselves offer their patented medicines to different customers at different prices, thereby realizing a large profit margin from sales to the more affluent without forgoing sales to poorer buyers at lower margins. A third variant is the right of governments, recognized under TRIPS rules, to issue compulsory licenses for inventions urgently needed in a public emergency. Exercising this right, a government can force down the price of a patented invention by compelling the patent holder to license it to other producers for a set percentage (typically below 10 percent) of the latter’s sales revenues. The US claims this right under 28 USC 1498 particularly for cases where the licensed producer is an agency of, or contractor for, the government—but has been reluctant to invoke the right in the case of medicines, presumably to avoid setting an international precedent detrimental to its pharmaceutical industry. Thus, during the anthrax scare of 2001, the US preferred to pressure Bayer into supplying its patented drug CIPRO for US$0.90 per pill (versus a wholesale price of US$4.67) over purchasing generic versions from Polish or Indian suppliers. Canada did invoke compulsory licensing in that case, but backed down under pressure four days later (www.cptech.org/ip/health/cl/cipro). It is often suggested that poor countries
should assert their compulsory licensing rights to cope with their public health crises and with the AIDS pandemic in particular. A number of poor countries have issued compulsory licenses, but the discouragement from the US and other rich countries (n. 24) is such that most poor countries are not availing themselves of this option.

It is common to find products being sold at different prices to different groups of consumers. Nonetheless, differential pricing solutions cannot overcome the second market failure arising from monopoly patents without bringing back the first market failure of undersupply. The reason for this consists in the combination of two factors. The first factor is the magnitude — in both relative and absolute terms — of the price differential involved. In order to incentivize pharmaceutical innovation, prices charged affluent patients must be quite high: many times more than the long-run marginal cost of production. Yet, in order to ensure access by the world’s poor, the price they are charged must be low: not much above marginal cost. Such huge price differentials — where a treatment supply for a month costs, say, $100 in Mexico and $3000 in the US — are difficult to enforce because they create strong incentives to divert (e.g., smuggle) to rich countries medicines intended for the poor. These incentives are especially strong because pharmaceutical products are small and light-weight relative to their retail value in the affluent countries. It is difficult to block diversion, and impossible to prevent the various categories of suppliers, retailers, and buyers from knowing about one another. Patent holders seeking additional profits through cheaper sales in poor countries thus run the risk of finding their (in any case insubstantial) gains greatly outweighed by profits foregone in rich-country markets due to diversion. Mindful of this risk, patent holders typically do not themselves try to overcome the second market failure through differential pricing, resist pressures to do so, and fight attempts to impose compulsory licensing upon them. As a result, differential pricing has not gained much of a foothold, and many poor patients who would be willing and able to purchase the drug at a price above the long-run marginal cost of production are excluded from this drug because they cannot afford the much higher monopoly price.35

To be sure, insofar as a government succeeds, against heavy pressure from pharmaceutical companies and often their governments, in exercising its right to issue a compulsory license, any net losses due to diversion are simply forced upon the patent holders. But such compulsory licensing, especially if it becomes more common, brings back the first market failure of undersupply: Pharmaceutical companies will tend to spend less on the quest for essential medicines when the uncertainties of successful development, testing, and regulatory approval are compounded by the additional unpredictability of whether and to what extent companies will be allowed to recoup their investments through undisturbed use of their monopoly pricing powers.
Finally, and most importantly, differential pricing solutions cannot end the neglect of diseases that very rarely strike the affluent. Differential pricing can help give the poor access to a medicine at competitive market prices only if this medicine exists. And this medicine will exist only if there is enough market demand for it also among the affluent who, by being willing to purchase the medicine at monopoly prices, make an investment in its development profitable. Nearly all diseases and research avenues neglected under the current regime would continue to be neglected under a differential pricing regime.

5 The public-good strategy for extending access to essential medicines

In light of these serious problems, it is uncertain whether the differential-pricing strategy can yield a reform plan that would constitute a substantial improvement over the present regime. So I am proceeding on the assumption that an exploration of the public-good strategy is more promising, that is, more likely to lead to the formulation of a reform plan that would avoid the main defects of the present monopoly-patent regime while preserving most of its important benefits. The great difficulty lies in devising an attractive and workable reform plan within this much larger domain of the public-good strategy.

We may think of such a reform plan as consisting of three components: open access, alternative incentives, and funding. First, the intellectual results of any successful effort to develop (research, test, and obtain regulatory approval for) a new essential medicine are to be provided as a public good so that all pharmaceutical manufacturers may produce this drug without permission from or payment to the innovator. This reform would eliminate the second market failure (associated with monopoly pricing powers) by allowing competition to bring the prices of new essential medicines down close to their long-run marginal cost of production. Implemented in only one or a few countries, this reform would engender problems like those we have found to attend differential-pricing solutions: Cheaper drugs produced in countries where drug development is treated as a public good would seep back into countries adhering to the monopoly-patent regime, undermining research incentives in the latter. The reform should therefore be global in scope, just as the rules of the current TRIPS regime are. The first reform component is, then, that intellectual results of successful efforts to develop new essential medicines are to be provided as public goods that all pharmaceutical manufacturers anywhere may use without permission from or payment to the innovator.

Implemented in isolation, such open access would destroy incentives for pharmaceutical research. To avoid this effect, inventors must be offered some alternative reward. This second
component of the reform plan can be specified in different ways. These ways can be loosely categorized as “push” and “pull” programs. A push program selects and funds some particular innovator — a pharmaceutical company, perhaps, or a university or a national health agency (like the National Institutes of Health in the US) — to undertake a specific research effort. The idea here is that, given 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 all potential innovators, promising to reward whoever is the first to achieve a valued innovation. Pull programs have two interrelated advantages over push programs: They never pay 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 gets there 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 research and development effort. In these respects, a pull program is similar to the current regime.

Suppose, for instance, that the decision of a pharmaceutical company, C, about some specific research effort is informed by the following expectations about its three possible outcomes: There is a 25-percent chance that C will be the first to succeed at an estimated cost of between $44 and $60 million. There is a 60-percent chance that a competitor will get there first at a time when C will already have incurred or committed to expenditures between $10 and $60 million. There is a 15-percent chance that C will find that it just cannot succeed at a time when C will already have incurred or committed to expenditures between $20 and $60 million. Assuming a symmetrical distribution of probabilities in the three expenditure ranges, this company will value the expected cost of its potential research effort at $40 million. To match this expected cost, the reward would have to be valued at $160 million. Since the research effort involves risk as well as loss of the use of company funds in the interim, C will rationally undertake the effort only if it values the reward at considerably more than $160 million. In this example, an effective pull program would have to offer a reward valued at around $200 million in order to elicit a research effort costing about a quarter as much. A push program would instead pay around $60 million to one selected innovator.

Despite this considerable differential, pull programs can be more effective than push programs nonetheless, 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. 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. The disadvantage that push programs are more likely to fail is compounded by the fact that such failures are fully paid for — in contrast to pull programs which pay nothing for failed efforts. This fact tends to make push programs more difficult to sustain politically.

There is no general answer to the question of whether the public-good strategy is best pursued with push programs or with pull programs. Programs of either type may be superior in different contexts, and it is important that the public-good strategy can draw on both types. In what follows, I explore the pull option, for two reasons. It fits better with the private enterprise/free market spirit that increasingly pervades economic life worldwide. And pull programs are also politically more sustainable by generating industry support and by assuring taxpayers that none of their money is funding failed research efforts.

Currently most popular within the category of pull programs are prizes that offer fixed rewards for the innovator who first produces a medicine that meets certain specifications. The reward is typically formulated either as some monetary amount or as an advance purchase commitment to buy a fixed number of doses of the new medicine at a pre-set price. Such prizes have been described with considerable ingenuity. They clearly can be a valuable complement to existing monopoly-patent rewards and have the potential of stimulating the development of medicines for currently neglected diseases.

Nonetheless, prizes have four serious draw-backs. First, politicians, bureaucrats and experts play a substantial role by deciding which diseases ought to be researched, how to specify the remedy to be aimed for, and how large a reward should be offered 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, lobbying by companies and patient groups, and gaming. 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 impact of their efforts. Given weak incentives and poor information, the planners’ design of prize competitions would likely be seriously suboptimal.
This problem is compounded by a problem that arises from the fact that prizes involve excessive specificity. A prize 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, to specify the prize optimally in these various dimensions, the planners would need the very knowledge whose acquisition their prize is going to encourage. Since they lack this knowledge ahead of time, their specification is likely to be seriously sub-optimal even if they are single-mindedly devoted to the goal of improving public health. Such sub-optimality can take two forms. The planners may be too demanding with respect to at least one parameter, with the result that firms give up the effort even though something close to the sought solution is within their reach. And the planners may be insufficiently demanding with respect to some parameter(s), with the result that firms, 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.  

The further disadvantage of prizes is that the funding they depend on is likely to be haphazard and case-by-case. This is so because arbitrary and political factors 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 because governments, when encountering budget problems, will tend to skip or to postpone planned prize competitions and because 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 need to “get rid of” in the current year to retain their tax-deductible status).

A fourth and very serious defect of prizes is that they fail to address the “last-mile” problem, which is especially serious in the context of currently neglected diseases that mostly affect the poor. The fact that a new essential 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 (cf. text at n. 44). This thought shows that prizes are not really a pull solution in the full sense. Prizes pull innovators to the invention of a new safe and effective medicine or even to its production in large quantities. But they do not pull this medicine the rest of the way to the patients who need it.  

6 A full-pull plan for the provision of pharmaceuticals
Let me introduce the essentials of a pull program that overcomes these four defects. The basic idea is to institute — complementary to existing monopoly patents — a new kind of patent for essential medicines that entitles the patent holder, during the life of the patent, to be rewarded out of public funds in proportion to the impact of the invention on the GBD. This idea of a novel “patent-2” avoids the first two draw-backs of prizes by leaving innovators themselves, rather than outside experts and bureaucrats, in charge of the direction of their research. Innovators are not told what to invent. Rather, each potential innovator is incentivized to undertake whatever research it itself believes to be the one through which it can most cost-effectively contribute to GBD reduction. Under a full-pull scheme, pharmaceutical research is driven by the uncoordinated decisions of competing innovators rather than by the guesses and interests of political planners. A full-pull scheme replaces a central-planning solution with a competitive-market solution.

A full-pull scheme avoids the third draw-back of prizes by presenting a systemic, market-structuring solution that, once incorporated into the global institutional architecture, covers all serious health problems for the indefinite future. Much more independent of the vagaries of legislative appropriations or donor priorities, such a scheme simply rewards what works in proportion to how well it works. The profits of biotechnology and pharmaceutical companies are driven by how their work affects human health worldwide.

A full-pull scheme avoids the fourth defect of prizes by basing rewards on what really matters: on actually observed reductions in the GBD. Only in this specification can the public-good strategy effectively secure to the poor the real access to essential drugs that is so dramatically lacking under the existing patent regime. A full-pull scheme would reorient the incentives of innovators in highly desirable ways:

— Any patent holder would have reason to encourage, support, and even subsidize efforts by cheap generic producers (already well-established in India, Brazil and South Africa, for example) to mass-produce its drugs, because such manufacture would enhance affordability and availability of its medicines to poor patients and hence their favorable impact on the GBD. This harmony of interests contrasts sharply with the present regime which engenders massive waste from costly litigation that pits generic companies, with strong incentives to challenge any patent on a successful medicine, against patent holders, whose earnings are driven by their ability to defend, extend, and prolong their monopoly rents. Generic companies have no incentive to challenge a patent-2, because they are free to replicate the patented medicine even without such a challenge — which is exactly what the patent-2 holder wants them to do.
— More broadly, a patent-2 holder has incentives to ensure that all who can benefit from its medicines have real access to them. Such a firm would then try to ensure that its innovative medicines are sold cheaply, perhaps below their marginal cost of production, in order to make them affordable to even very poor people who need them. Lower prices for advanced medicines benefit poor and affluent alike by reducing what they pay for drugs, insurance, and/or their national health system and also by reducing greatly the incentive criminally to manufacture and market fake drugs that may be ineffective or unsafe.

— A patent-2 holder has reason to confine its marketing efforts to people whom its medicine can actually benefit. Its reward depends not on doses sold or even on doses taken, but solely on health impact which, when the drug is not indicated, might actually be negative). This desirable incentive is wholly lacking in the present regime, which gives patent-1 holders powerful incentives to “hype” their medicine so as to get it to be used even by people whom it would not benefit and who might even be harmed by it.

— While the present patent regime strongly biases research in favor of new treatments and against new cures and vaccines (the most lucrative patients are those forever dependent on their daily dose), a full-pull scheme would sustain no such bias and would focus potential innovators solely on developing those medicines that reduce the GBD in the most cost-effective way. This would lead to more efficient health care provision everywhere — and also to better health (through medicines that make people independent from continuous drug intake).

— Any inventor firm would have incentives also 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 maximum public health impact. The lack of such incentives under the present regime (which prizes would not remedy) gravely undermines the effectiveness of drugs delivered into poor regions, even when these drugs are donated. Defective compliance causes and accelerates the evolution of drug-resistance which can greatly aggravate the risks and health burdens a disease causes to both poor and affluent populations (multi-drug-resistant tuberculosis is a prime example).45

— Rather than ignore poor countries as unlucrative markets, inventor firms would moreover have incentives to work together toward improving the health systems of these countries in order to enhance the impact of their inventions there.

In all these ways, the reform would align and harmonize the interests of inventor firms with those of patients and of the generic drug producers — interests that the current regime brings into sharp opposition and that would at best be orthogonal under a prize regime. The reform would also align
the moral and prudential interests of the inventor firms. Under the present regime, by contrast, such firms reap the greatest rewards when they work to deprive the poor of access to essential drugs at lower prices and shun research into poverty-specific diseases. Even under a prize regime, any effort by innovators to enhance the health impact of their rewarded inventions constitutes a loss to their bottom line.

Better than prizes, a full-pull scheme thus overcomes the most consequential moral defect of the status quo: Under the current regime, inventor firms have incentives to try to develop a new medicine only if the expected value of the temporary monopoly pricing power they might gain, discounted by the probability of failure, is greater than the full development and patenting costs. They have no incentives, then, to develop medicines that few people would be able and willing to buy at a price substantially above the long-run marginal cost of production. A full-pull scheme overcomes this defect most decisively for currently neglected diseases that are severe and widespread (cf. nn. 28-31). It ties reward for pharmaceutical innovations to their impact on the GBD and thereby attracts inventor firms to diseases whose adverse effects on humankind can be reduced most cost-effectively. These new incentives to pharmaceutical innovators for joining the fight against some disease would be the stronger the more severe and the more common this disease is.47

One might worry that such new rewards would shift attention away from diseases that, though they add little to the GBD (on any plausible conception thereof), affluent patients are very keen to avoid. This worry can be addressed, at least in large part, by limiting the application of the reform plan to essential drugs, vital to health and survival. Drugs for other medical conditions, such as hair loss, acne and erectile dysfunction, for example, can remain under the existing monopoly patent regime with no loss in incentives or rewards. In this way, only a short-term adjustment problem remains: As the new rewards are introduced, innovators will forgo some of their only slightly profitable opportunities to develop non-essential drugs for more profitable new opportunities to develop essential drugs.48 But the biotechnology and pharmaceutical industries will also attract new capital and add research capacity in order once again to take advantage of all profit opportunities that are lucrative (relative to investment opportunities available elsewhere).

Incorporating a distinction between essential and non-essential drugs into the reform plan raises the specter of political battles over how this distinction is to be defined and of legal battles over how some particular invention should be classified. These dangers can be averted by allowing inventor firms to classify their inventions as they wish and then designing the rewards so that these firms will themselves choose to patent under the reformed rules any inventions that stand to make a substantial difference to the GBD. Such freedom of choice would also greatly facilitate a smooth and
rapid phasing-in of the new rules, as there would be no disappointment of the legitimate expectations of firms that have undertaken research for the sake of gaining a traditional monopoly patent. The reform plan should be attractive to biotechnology and pharmaceutical companies by winning them new profitable opportunities for research into currently neglected diseases without significant losses in the lucrative research opportunities they now enjoy — and by restoring their moral stature as benefactors of humankind.

The centerpiece of this full-pull variant of the public-good strategy is then the creation of a modified pharmaceutical patent that substitutes a reward proportioned to the invented drug’s impact on the GBD for the traditional reward of a temporary monopoly over this drug. This reform would not require a major restructuring of the existing patent regime. Existing application and award procedures for pharmaceutical patents could remain in place and merely be complemented by a standing option promised to any patent holder. This option is to renounce any veto powers over the manufacture of the patented medicine worldwide in exchange for title to a stream of reward payments proportioned to this medicine’s global health impact. By thus converting (as I will say) its patent-1 into a patent-2, the owner chooses to turn the centerpiece of its patented knowledge into a public good by making the new medicine available for free generic production worldwide. The owner retains all other proprietary rights to its invention.

This second reform component requires a way of funding the planned incentives for developing new essential medicines, which might reach a cost of around $45-90 billion annually on a global scale. (A more precise estimate is difficult because the cost each year would depend on how successful innovative medicines would be at reducing the GBD. The proposed scheme would cost serious money only if and insofar as it actually leads to reductions in the GBD.) The third component of the reform plan is then to develop a fair, feasible and politically realistic allocation of these costs. In accepting such an allocation, willing countries would commit to contributing a certain monetary amount per unit of GBD reduction. These country-specific amounts can be proportioned to gross national income (GNI) — with some progressivity perhaps according to per capita GNI so as to exempt the very poorest countries. This allocation should be enshrined in a specific and enforceable international treaty so as to provide maximum assurance to potential inventors. Doubts among biotechnology and pharmaceutical firms about whether promised rewards will actually materialize diminish the incentive effects of the scheme and thereby defeat its purpose.

A serious objection to the full-pull scheme as sketched is that it focuses exclusively on novel pharmaceutical solutions. There are many humanly controllable factors relevant to reducing the GBD, and access to medicines, however important, is only one of these. Other crucial factors are
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 should we reward only new pharmaceutical remedies when there are alternative, perhaps more cost-effective ways of averting the same diseases?

The answer is that we should not, and that the full-pull scheme I have sketched is not in fact confined to novel pharmaceutical solutions. Once a firm has obtained a patent-2 for 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). Many other causal factors, besides the quality of the new drug, may influence its impact. It is not possible to disentangle, in a reliable and transparent way, the effects of all these many factors. The best way of handling this complexity is then to assess the impact of the new drug against mortality and morbidity projections made for the target disease before this drug became available.

In this way, patent-2 holders are held responsible, as it were, for causes beyond their control — the weather, for instance, which may affect the prevalence of disease-carrying mosquitoes. But the same is true for firms that invest in the production of heating oil or garden furniture. These are the ordinary risks of enterprise which, over many geographical regions and the many years of the patent period, will tend to be reasonably predictable. Moreover, firms can hedge against these risks in various ways, for example through insurance. Patent-2 holders are also held responsible for relevant humanly controllable factors they can affect — for example, the quality of health care delivery in poor countries. By helping to improve such health-care delivery, a patent-2 holder can magnify its medicine’s impact, which is strongly affected by whether doctors and nurses are reachable by patients, 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.

Better access to nurses and doctors will invariably have other desirable effects on the relevant population, over and above better provision of the patent-2 drug. It will, in particular, enable people better to protect themselves against contracting diseases in the first place. By helping to improve health-care delivery, a patent-2 holder will thus reduce the incidence of the target disease also in ways that do not involve (and even decrease the need for) its medicine. Such reductions are welcome, and there is no reason for making them ineligible for reward. We may then conceive a patent-2 so that it gives its owner a somewhat broader stake in the (less detrimental than projected) evolution of the target disease, rather than merely in harms from this disease that were averted directly through use of the patented medicine. This feature of the reform plan evidently needs to be further specified for cases where two or more firms have patent-2 drugs that target the same disease (I address such
cases in the next section) or where efforts by patent-2 holders are enhanced or complemented by public agencies or NGOs.

One may wonder whether patent-2 holders — mainly pharmaceutical and biotechnology companies — have the capacity to overcome real-world obstacles to universal access to their medicines and to address other causal factors that affect how much harm is done by a target disease. As these companies are currently constituted, they indeed have no incentive whatever to think about, or to equip themselves to handle, such matters. They do have an interest, of course, that their drug should be effective in averting harm from paying customers. But the current patent regime gives innovators no incentive to reduce the global incidence of their target disease. On the contrary: If a patent holder’s medicine managed to eliminate its target disease, it would thereby destroy its own market! And insofar as a patent holder’s medicine reduces the incidence of its target disease, it shrinks its own market. The current patent regime ties the profits of patent holders to two factors: In order to profit optimally,

— the patent holder must have a medicine that is effective in protecting paying patients (or countries, in the case of a vaccinations program, for instance) from the target disease and/or its detrimental symptoms; and

— this target disease must continue to thrive and spread and, in particular, must not be decimated or eradicated by the patented medicine.

Contrary to what is often said, poor populations who cannot pay monopoly prices for the medicines they need are not then useless or irrelevant to the bottom line of patent holders. Rather, they serve the useful and profitable function of keeping alive the contagious diseases for which patent holders sell remedies at monopoly prices. If there weren’t large numbers of people without access to effective malaria protection, then affluent travelers would not buy such protection at monopoly prices — because malaria would then be no more threatening anywhere as it now is in Florida or Italy.

The present pharmaceutical patent regime is so perverse that pharmaceutical executives, insofar as they take seriously their fiduciary responsibilities to their shareholders and employees, have reason to do whatever they legally can do, and to omit whatever they can legally omit, to promote increases and to block reductions in the incidence of their target diseases among non-customers. This insight puts into perspective the (quite accurate) observation that such companies are ill-equipped to overcome real-world obstacles to universal access to their medicines and ill-equipped to address other causal factors that affect the impact of their medicines on the incidence of these medicines’ target diseases. The less of a reduction such a medicine effects in the incidence of its target disease, the greater and more sustainable are the profits opportunities of those who own the
patent for this medicine. That pharmaceutical and biotechnology companies are ill-equipped to magnify the impact of their drugs is not a natural fact about such companies, but a predictable consequence of how they are regulated and incentivized by the current patent regime. To adduce their current incapacities in defense of this regime is to argue in a circle.

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. It is our responsibility to restructure the patent regime so that pharmaceutical innovators lose the financial stake in the proliferation of their target diseases and gain a financial stake in the destruction and eradication of these diseases. If we can reverse present incentives, the immense powers of free enterprise will be marshaled against the great diseases that bring so much misery and premature death to poor people everywhere. It would be hugely to underestimate these powers of free enterprise to presume that well-organized, profit-oriented companies with stock market capitalizations in the hundreds of billions — Pfizer’s market capitalization of $190 billion is twice, and its 2006 sales volume of $48.4 billion is half, the combined GNIs of the 26 poorest African states with their 406 million inhabitants — would not know how to build an effective disease reduction strategy around their pertinent drugs in the world’s more challenging environments.

The response 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 those who reduce the GBD by addressing such diseases — by securing access to off-patent medicines, to clean drinking water or to sanitation, perhaps — be rewarded on a par with pharmaceutical innovators who contribute new medicines toward GBD reduction? Indeed, they should be. We can think of the present plan for reforming the rules governing pharmaceutical innovation as the central module of a larger health reform project. Once this central module is fully specified, it can certainly be extended, along similar lines, to other social factors essential to human health. It makes sense, nonetheless, to begin with the central module. Its full specification would provide a useful paradigm for possible extensions, and its implementation would provide an impetus for further reform.
But why start with *this* module, centering around new pharmaceuticals? Wouldn’t the money 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 bitter experience over many decades has shown that the rich countries are not prepared to spend tens of billions of Dollars on clean water or Plumpy’Nut supplies. In the world as it is, the idea of spending such amounts on combating severe poverty and disease abroad seems entirely incongruous. These objectives are thought to deserve a few millions here and there, but certainly no ten-digit amounts. The idea of spending such sums on supporting domestic corporations, by contrast, is entirely familiar and commonplace — in fact, the affluent countries are annually spending *hundreds* of billions on export credits and subsidies (which aggravate severe poverty abroad) in the agricultural sector alone. A politically realistic way forward might yoke these two objectives together through a plan that supports domestic corporations and also combats severe poverty and disease worldwide. The full-pull plan I have sketched is designed to fit this description. There may be better ways to spend the money this plan would cost. But such alternative plans are useless nonetheless if they fail to mobilize the funds they plan to spend. Aligning with the powerful interests of the pharmaceutical and biotechnology industries, our full-pull plan has better prospects for success.

7 *Specifying and implementing the basic full-pull idea*

While the basic full-pull idea may seem plausible enough, much work is still needed to specify it concretely in a way that shows it to be both feasible and politically realistic. The need to work out these specifications is not based on the naïve expectation that, once the plan is fully specified, the world’s governments will implement it as drafted. It is far more likely that governments — should they become interested in such a plan at all — would redraft it in protracted negotiations involving armies of experts. Specification is important nonetheless for proof of concept: for showing that there is at least one way of specifying the plan that can cope with the real-world complexities.

A successful specification of the reform idea requires, at a minimum, definition of an appropriate metric for the GBD, determination of a monetary reward per unit of GBD reduction, ways of collecting sufficient data to assess the GBD *ex post* and to make plausible baseline GBD projections some years into the future, rules for allocating a specific GBD reduction among contributing patent-2 holders, adequate mechanisms for curbing corruption and gaming, an internationally acceptable treaty-backed schedule for funding the rewards, and specific rules for the phase-in period.
We are hard at work at all these difficult problems, but a detailed preliminary report on this work here would take up too much space. Let me instead comment on the problems of specification and implementation in reference to the desideratum that the reform plan should be politically realistic. To be realistic, the plan must avoid opposition from, and indeed be appealing to, two existing constituencies: the biotechnology/pharmaceutical industry, and the more affluent populations who, as taxpayers, must contribute some fraction of one percent of their gross incomes to fund the plan.

Though people care more about health and longevity than almost anything else, the pharmaceutical industry is no more loved and admired than others. In fact, as regards public reputation, the big pharma companies are right down there with the tobacco and arms industries. This poor reputation is a substantial political liability. The complaints are well-known: too little genuinely innovative research, too much marketing and manipulation of doctors, price-gouging protected by monopoly patents, and homicidal enforcement actions against production, importation, and distribution of generics in poor countries.

It is said, and not without plausibility, that there is not much each pharmaceutical company can do on its own to stay clear of these complaints. These companies compete against one another, and any company acting “nicely” in more than marginal ways would lose ground against the others and ultimately be driven out of the market. It is then not an evil lust for blood-stained profits that causes tens of millions of premature deaths and unimaginable human misery. The cause is rather a collective action problem that harms the pharmaceutical companies, too, in terms of their reputation and profits. My hope is to remove the barriers that deprive the poor of access to essential medicines in a way that is also beneficial to the pharmaceutical industry. We need a regulatory reform that, rather than incentivizing pharmaceutical firms to deprive the poor of access to advanced medicines, incentivizes these firms to facilitate such access.

While pharmaceutical companies cannot solve the problem individually, under the existing rules, they can do much to help solve the problem collectively, through reform of these rules. The central defect in the existing rules, as we have seen, is the monopoly pricing power they employ, even in the case of essential medicines, to incentivize pharmaceutical research. By having monopolies as their sole reward, pharmaceutical companies are put in a morally untenable position: To engage in sustainable research and development of essential medicines, they must actively prevent poor people from gaining access to such medicines near marginal cost. This quandary can be overcome only through a change in the rules that would create new rewards for the research and development of essential medicines.
Those who derive great profits from their intellectual property regard any reform of the existing intellectual property rights regime as a Pandora’s box that they are loathe to open. Pharmaceutical companies can line up behind a reform proposal, but once reform deliberations get underway in national and international political fora, there is no guarantee that their proposal will be adopted. Safer then, perhaps, to leave things as they are — though this route risks building further anger and resentment among those who bear, or care about, the horrendous suffering the current regime is inflicting. Even greater wariness of reform characterizes the corporate members of the other industries that were part of the grand pro-TRIPS coalition: the software industry, the entertainment industry, and the agribusinesses. These companies, and their owners and executives, do not like to see millions of people sacrificed on the altar of monopoly enforcement. Yet, seeing themselves as even less implicated in this catastrophe, they are even more reluctant than their pharmaceutical counterparts to endanger an exceedingly abundant income stream for the sake of stopping this sacrifice.

For reform to have any chance of political success, two elements are crucial. First, the reform must have a clearly limited objective: It concerns only essential medicines — not other pharmaceuticals, nor software, music, movies, fertilizers or even seeds. And it is non-threatening to the profits of pharmaceutical innovators by always leaving them free to opt for a traditional patent-1: it wins for them new opportunities for profitable and morally urgent research and development without losing any profit opportunities they currently enjoy. Second, the relevant industries, and the pharmaceutical industry especially, must be assured that the reform process will observe these limits. This second element is very difficult to supply. It requires that many of those who find the present exclusion of the poor from advanced medicines intolerable unite behind a common reform plan that clearly recognizes and accepts the limited focus on essential medicines. A modest reform plan, supported by a broad global coalition that goes well beyond the pharmaceutical industry, could give this industry the confidence to throw its full support behind it. To build such a coalition, we must convince ordinary citizens to support the plan even though it requires public funds — a task discussed in the next section. We must also convince more-radical reformers (prominent in many health-related NGOs) to support the plan even though it preserves monopoly patents and expands the profit opportunities of the pharmaceutical industry.

Let me conclude this section by reiterating that the full-pull reform plan is based on the conviction that we will reach our common and imperative goal of universal access to essential medicines either in collaboration with the pharmaceutical industry or not at all. Such collaboration begins in the specification stage. The rules of the full-pull plan must be designed to be clear and
transparent, lest they add to the inevitable risks and uncertainties that complicate the work of inventor firms and sometimes discourage them from important research efforts. Along with frontline medical professionals and statisticians, pharmaceutical companies can be especially helpful in designing rules for allocating rewards for specific GBD reductions among contributing pharmaceutical innovators. These rules must, first of all, provide a plausible method for demarcating the causal contributions that various diseases are making to the GBD, coping here with interacting causes of death and disease as well as with subjunctive causes.\textsuperscript{53} And they must then provide plausible rules for crediting reductions in these contributions to various pharmaceutical innovations. These latter rules must cope with cases where patent-2 drugs invented by different firms address the same disease, either as alternative interventions or through a joint intervention (such as a “drug cocktail” like those now used in the fight against HIV, tuberculosis, and malaria). In both these cases, public health methods of counterfactual analysis will be informative. But counterfactual analysis by itself cannot determine the allocation because (to name just one reason) it typically does not provide “additive decomposition,” that is, the GBD reductions counterfactual analysis attributes to different causes do not add up to the total GBD reduction these causes together achieve. There are different ways of resolving this issue and different ways of allocating rewards among earlier and later contributors. No resolution is natural or obvious, and the reform plan will then feature a methodological convention selected in part on pragmatic grounds.

Our team will provide a model solution, of course. But one beauty of the full-pull scheme lies in the fact that the actually implemented solution can be worked out with the pharmaceutical and biotechnology industries. Once a monetary reward per unit of GBD reduction has been specified, the full-pull scheme secures a harmony of interests in regard to allocation rules. The citizens funding the plan want it to be successful by achieving as great as possible a reduction in the GBD. And so do the inventor firms, for the additional reason of maximizing their profits. Since these companies negotiate under a virtual veil of ignorance with respect to as yet uninvented medicines, their collective interests will shape their negotiating strategy. They will want to design the allocation rules so as to maximize their collective harvest of rewards. In particular, they will want these rules to be clear and transparent so as to reduce uncertainty. They will want the incentives to be shaped so as to foster efficient collaboration and synergies among themselves. They will want to set up a cheap and reliable arbitration mechanism so as to avoid costly disputes.\textsuperscript{54} There is then considerable harmony of interests not merely in the operation of the plan, but already in its specification — lending further support to the claim that its central idea is not merely feasible but also politically realistic.
Many in the affluent countries will readily agree with me that a reform that would save millions of lives each year and would protect billions of human beings from contagious diseases is morally imperative, especially when it would cost only a fraction of one percent of global income. But, in order to achieve such a reform politically, we must agree on one specific and politically realistic reform plan. Our human world is so perversely organized that there are many plausible reform avenues that promise huge moral gains at small financial cost. This is good in one sense: it is neither difficult nor expensive to end systemic world poverty once humanity musters the collective political will to do this. But it is bad in another sense by making it much harder to coordinate on one common reform strategy.

The unjust rules we are seeking to reform exist because others have managed to coordinate in their support. The agribusiness, software, entertainment, and pharmaceutical industries have overcome their differences to throw their political clout behind a joint (TRIPS/TRIPS-plus) strategy that — together — they got their governments to impose on the world. Those seeking to protect the poor have undeniably made great and often successful efforts of many kinds. But we have not managed to coordinate on a joint political strategy, and our dispersed efforts are therefore greatly hampered by the powerful and continuous impoverishing impact of unjust institutional arrangements. With great and unceasing effort we can hope continuously to neutralize some of this headwind from unjust rules. With an intelligent political mobilization we could reform these rules and thereby truly eradicate world poverty. Thus far, we have done poorly on this second, political front. We continue to speak with myriad voices and put forth a chaotic heap of half-baked reform ideas many of which would be politically unrealistic even if we managed to coordinate behind them.

Here is then my justification of the reform plan to those who are committed to end the structural injustice that perpetuates world poverty: Accommodating the interests of the pharmaceutical and biotechnology firms, the full-pull plan is politically realistic — vastly more so than any other plan of comparable magnitude. Its implementation would lift an enormous burden off the global poor, thereby enabling them to be much more effective allies in their own emancipation. Implementation of the plan would also establish a model that can be replicated to eradicate other factors in the perpetuation of poverty: the lack of clean water, of adequate sanitation, of shelter, of basic education, and of minimally adequate employment. The full-pull idea, once up and running in the domain of pharmaceuticals, would motivate complementary reform efforts in these other domains.
To win governments to implement the plan, we must show them that it can find support from their constituents, corporations and citizens. I have said a lot about how the plan can appeal to the pharmaceutical and biotechnology industries. Let us now consider how it can appeal to ordinary citizens who are worried about its cost and feasibility.

Earlier I have estimated that the annual cost of the plan might peak at around $45-$90 billion. With all the world’s countries participating, $45 billion amounts to 0.1 percent and $90 billion to 0.2 percent of the 2005 global product. These figures remain essentially unchanged even if the poorer half of the human population is exempted, because their aggregate income is under 2 percent of the global product. (Using 2005 figures, exempting them reduces the “tax base” from $45 trillion to $44 trillion, a negligible reduction.) These percentages rise, however, when we assume that some countries will refuse to participate. If merely the US, representing about 30 percent of the global product, failed to participate, taxpayers in the remaining countries would face a peak contribution of between 0.14 and 0.28 percent of their gross incomes. If countries representing half the global product failed to participate, the remaining taxpayers would face a peak contribution of between 0.2 and 0.4 percent of their gross incomes. If countries representing two-thirds of the global product failed to participate, the remaining taxpayers would face a peak contribution of between 0.3 and 0.6 percent of their gross incomes. What can be said to skeptical taxpayers, especially in the more affluent countries, to convince them to support such a contribution?

This expense can be supported by prudential considerations. It is true that the plan would make the greatest difference to diseases that are widespread and concentrated among the poor. Yet the plan’s reach would also extend to most of the serious diseases common among the more affluent. One important reason for this is that these diseases will foreseeably become more common among the poor as the full-pull plan succeeds in decimating the great scourges that now account for most of their mortality and morbidity. Pharmaceutical innovators can predict that a rapid decline in contagious diseases would, via extended life expectancy, be associated with further increases in the incidence among the poor of the ailments (like heart disease) now common among the more affluent. And this prediction gives them reason to choose patent-2 for more of their new essential medicines. Even if profit \textit{per patient} is substantially larger with a traditional patent-1, in many cases choice of patent-2 would enable pharmaceutical innovators to earn a larger \textit{overall} profit by serving a much larger patient population. (Insofar as pharmaceutical innovators would be uncertain about which patent would yield greater profits, many would be inclined to choose patent-2 because they want to be, and to be seen as, contributors to global health when this is economically feasible.) By helping to fund the development of cheap patent-2 medicines, taxpayers of the wealthier countries thus gain a
substantial benefit for themselves in the form of lower drug prices, lower insurance premiums, and/or lower national health care outlays. To be sure, such a shifting of costs, within affluent countries, from patients to taxpayers would benefit less-healthy citizens at the expense of healthier ones. But this mild mitigation of the effects of luck is actually morally appealing — not least because even those fortunate persons who never or rarely need to take advantage of advanced medicines still benefit from pharmaceutical research which affords them the peace of mind derived from knowing that, should they ever become seriously ill, they would have access to superb medical knowledge and medicines.

A second prudential reason is that, by making pharmaceutical research sensitive to the interests also of poor populations, we are building good will in the poorer countries by demonstrating in a tangible way our concern for their horrendous public-health problems. This argument has a moral twin: In light of the extent of avoidable mortality and morbidity in the poorer countries, the case for including the interests of the poor is morally compelling.

These last twin arguments have wider application. The reform plan would not merely encourage the same pharmaceutical research differently, but would also expand the range of medical conditions for which inventor firms would seek solutions. Under the current regime, these firms understandably show little interest in tropical diseases, for instance, because, even if they could develop effective medicines, they could not turn a profit by selling or licensing them. Under the alternative regime I suggest we design, inventor firms could make substantial profits by developing such medicines whose potential impact on the GBD is enormous. Measles, malaria, and tuberculosis each kill well over a million people per year, mostly children, and pneumonia kills more than the other three combined. New drugs could dramatically reduce the impact of these diseases.

There are three further prudential reasons. The reform would create top-flight medical-research jobs in the affluent countries. It would enable us to respond more effectively to future public health emergencies by earning us more rapidly increasing medical knowledge combined with a stronger and more diversified arsenal of medical interventions. In addition, better human health around the world would reduce the threat we face from invasive diseases. The SARS outbreak and the avian flu scare illustrate the last two points: Dangerous diseases can rapidly transit from poor-country settings into cities in the industrialized world; and the current neglect of the medical needs of poor populations leaves us unprepared to deal with such problems when we are suddenly confronted with them.
Bringing enormous reductions in avoidable suffering and deaths worldwide, the reform would furthermore be vastly more cost-effective and also be vastly better received in the poor countries than similarly expensive “humanitarian interventions” we have undertaken in recent years and the huge, unsustainable loans our governments and their international financial institutions tend to extend to (often corrupt and oppressive) rulers and elites in the poorer countries. Finally, there is the important moral and social benefit of working with others, nationally and internationally, toward overcoming the morally preeminent problem of our age, which is the horrendous, poverty-induced and largely avoidable morbidity and mortality in the less developed countries.

Let me reinforce this last point with a small exercise in moral mathematics. We are occasionally confronted by advertisements that invite us to give some small amount of money to save a child’s life. Leaving aside how reliable such invitations are, they may challenge us to ask how much we would be willing to give to save the life of a total stranger. Take some very conservative figure, some amount that you would definitely be willing to sacrifice (if this is the right word) to save a distant child’s life. Now ask yourself whether you should support your country’s joining the full-pull plan. On a very high estimate — which assumes that this plan works well enough to cut the GBD by half and that some very affluent countries fail to participate — your country’s participation might cost you, in the peak years, 0.6 percent of your gross income. Divide this figure by the 9 million premature deaths averted annually and you will find (assuming your annual gross income is below $150,000) that by supporting the plan you are agreeing to pay less than one-hundredth of a cent per death averted — and this without even counting all the horrendous suffering avoidable diseases inflict over and above the deaths they cause. To be sure, the plan may well be less successful in reducing the GBD. But its cost-benefit ratio is constant regardless of success: If the plan is only one-fifth as successful (reducing the GBD by one tenth) it would cost you only one-fifth as much.\textsuperscript{56}

The calculation assumed that countries representing two-thirds of the global product will refuse to join. It seems more likely, however, that if the plan were to be implemented at all, it would generate greater participation. It is true: If the plan’s benefits to users, manufacturers, and inventors of new medicines and to public health are global, then some countries could be free-riders. But few countries would find it morally bearable and politically opportune to adopt this role, especially if the patent-2 regime would exclude the biotechnology, pharmaceutical, and generic companies of non-participating countries.

With support from the US and/or the European Union, joined by dozens of developing countries, the full-pull plan could be worked into the global economic architecture by the end of this decade.
9 Conclusion

A particular scheme of rules for incentivizing pharmaceutical innovation has been imposed on the world over the past 15 years. Under this scheme, large financial rewards for pharmaceutical innovators are made to depend on their researching and developing new medicines for the affluent, on their blocking cheaper access by the poor to such medicines, and on the continued proliferation of their target diseases among the poor. Tens of millions die prematurely and billions suffer severely because patents make it impossible to supply them with competitively priced essential drugs that generic manufacturers are ready and eager to deliver.

This scheme is often defended by pointing out that, without strong incentives, there would be little or no pharmaceutical innovation and the misery of the poor would then be the fate of all of humankind. We have seen that this defense, based on a false dichotomy, fails. We have seen that there is an alternative global scheme for incentivizing pharmaceutical innovation that would extend the protection afforded by new medicines immediately to all human beings and would thus be much better at suppressing and eradicating (esp. infectious) diseases. This alternative scheme is feasible. And it is also politically realistic by protecting and increasing the profit opportunities of biotechnology and pharmaceutical companies and by imposing at most a small cost (relative to the existing unjust scheme) on the healthiest and most affluent segments of the human population.

This essay has shown that many premature deaths and much human misery are also avoidable through global health system reform that would make advanced medical knowledge freely available as a global public good. The rules should be redesigned so that the development of important new drugs can be rewarded in proportion to its health impact rather than through monopoly rents. This reform would bring prices of patented essential medicines worldwide close to their long-run marginal cost of production, would powerfully stimulate pharmaceutical research into currently neglected diseases, and would boost medical services available to the poor. Its feasibility shows that the existing pharmaceutical-patent regime (TRIPS as aggravated by bilateral agreements) is severely unjust on account of the avoidable mortality and morbidity it foreseeably produces.

Even if the proposed reform of the global health system involves opportunity costs for us, we ought to support it insofar as it is necessary for rendering minimally just (in the sense of “realizing human rights insofar as this is reasonably possible”) the rules of the world economy considered as one scheme. Justice in this minimal sense is compatible with these rules being designed by, and with their greatly and disproportionately benefiting, the governments, corporations, and citizens of the
affluent countries. Minimal justice is not compatible, however, with these rules being designed so that they foreseeably result in a much higher incidence of severe poverty, mortality, and morbidity than would be reasonably avoidable. By helping to impose the present global institutional order, we are participants in the largest human rights violation in human history. By supporting its reform along the lines I have sketched, we can take a great and highly cost-effective step toward eradicating systemic poverty in our lifetimes.
Bibliography


In 2002, there were 57,029 million human deaths. The main causes highly correlated with poverty were (with death tolls in thousands): diarrhea (1,798) and malnutrition (485), perinatal (2,462) and maternal conditions (510), childhood diseases (1,124 — mainly measles), tuberculosis (1,566), malaria (1,272), menengitis (173), hepatitis (157), tropical diseases (129), respiratory infections (3,963 — mainly pneumonia), HIV/AIDS (2,777) and sexually transmitted diseases (180) (WHO, The World Health Report 2004, pp. 120-5).

Such morbidity is due to the conditions listed in n. 1 as well as many other communicable diseases, including dengue fever, leprosy, trypanosomiasis (sleeping sickness and Chagas disease), onchocerciasis (river blindness), leishmaniasis, Buruli ulcer, lymphatic filariasis, and schistosomiasis (bilharzia). See Gwatkin and Guillot, The Burden of Disease.


UNDP, Report 2003, 310-30; UNRISD, Gender Equality; Social Watch, Unkept Promises.


Barnard, “In the High Court of South Africa.”

During the life of its primary patent, the patent holder can take out additional patents on a wide range of often trivial or irrelevant aspects of a successful drug, such as its packaging or dosing regimen. Having been applied for later, these further patents outlast the primary patent. They ensure that, even after the primary patent expires, the patent holder retains the right to be notified by any firm planning to commence generic production of the drug. Once notified, the patent holder can then deter or at least greatly delay generic production by asking for a 30-month stay (multiple such stays were permitted and practiced before August 2003), by paying the first generic patent challenger to “park” its 180-day exclusivity, and by threatening or initiating legal action that, regardless of its merit, can delay commencement of generic production by several years. The pharmaceutical industry’s anti-competitive practices are documented by the Federal Trade Commission in “Generic Drug Entry Prior to Patent Expiration: An FTC Study,” July 2002 (www.ftc.gov/os/2002/07/genericdrugstudy.pdf). See also NIHCM Foundation, Changing Patterns of Pharmaceutical Innovation, May 2002 (www.nihcm.org/finalweb/innovations.pdf); and the GAO report “New Drug Development” (p. 34): “Some analysts specifically highlighted the practice commonly known as producing line extensions — deriving new products from existing compounds by making small changes to existing products, such as changing a drug’s dosage, or changing a drug from a tablet to a capsule. According to analysts, these changes are typically made to blockbuster drugs shortly before their patents expire.”

Such provisions force potential generic producers to run wasteful new trials to document the safety and effectiveness of the medicine they plan to manufacture by preventing them from invoking, even after expiration of the patent, the data originally submitted by the patent holder. See MSF, Data Exclusivity.

Among the pharmaceutical research tools for which patents have been granted are expressed sequence tags (ESTs), restriction enzymes, screening systems, techniques related to DNA sequencing, and single nucleotide polymorphisms (SNPs). Such patents substantially impede
research and free competition. For details, see Rai and Eisenberg, “Bayh-Dole Reform and the Progress of Biomedicine.”

10 Kevin Outterson has challenged the use of the loaded expression “free rider” in contexts where very poor people enjoy some public benefit at no cost to anyone. He proposes that we speak of “fair followers” instead. See Outterson, “Fair Followers.”


12 See also Kuflik, “Moral Foundations of Intellectual Property Rights,” and Sterckx, “The Ethics of Patenting,” for more elaborate objections to the natural-right account of intellectual property.

13 This pattern emerged in the US after Congress in 1980, to encourage industry-use of government-funded inventions for consumer benefit, passed the Bayh-Dole Act which enables pharmaceutical companies, professors, and clinicians to cash in on patented applications of basic research done at universities or at the National Institutes of Health. For a brief account with further references, see Rai and Eisenberg, “Bayh-Dole Reform and the Progress of Biomedicine.” Private funding for biomedical R&D has overtaken public funding in the 1990s but public funding remains significant. See Moses et al., “Financial Anatomy of Biomedical Research,” p. 1336; Light, “Basic Research Funds to Discover New Drugs”; Research!America, “2005 U.S. Investment in Health Research” at www.researchamerica.org/publications/appropriations/healthdollar2005.pdf; and Angell, The Truth about the Drug Companies, pp. 7-8, 22-7, 56-76.

14 Nozick, Anarchy, State, and Utopia, p. 181. The Lockean proviso requires that unilateral appropriations are permissible only if they leave “enough and as good” for others. See Locke, “An Essay Concerning the True Original,” §27 and §33.

15 Nozick, Anarchy, State, and Utopia, p. 182.

16 Suppose many, knowing what a gourmet John is and hoping to free-ride on his efforts, refrain from creative culinary experiments they would otherwise undertake. I am not denying that Kant, Locke, and even Nozick provide good reasons for finding such conduct morally objectionable. My point is that such conduct escapes what all three thinkers regard as a narrower criticism: the charge that it violates a right of John’s. I also hold that Nozick, at least, is committed to the view that a right of the aspiring free-riders would be violated if they were for John’s sake prevented from mixing their own mushrooms into their food. I thank Andrew Williams for clarifying discussion on this point.

17 I leave aside here the special issues that arise for works of music, literature, and computer programming. These are central in Shiffrin, “Lockean Justifications of Intellectual Property Rights.”

18 A largely parallel argument can be made about medical innovations that do not involve special materials: acupuncture, for instance. Here, too, the innovator has a libertarian right not to share her discovery — even if this discovery could prevent great pains of many — but no right to ownership of the type. Nothing she does unilaterally can limit what others may do, with needles they legitimately own, to their own bodies.

19 See the GAO and FTC studies cited in n. 7; also Goozner, The $800 Million Pill, ch. 8, and Angell, The Truth about the Drug Companies, ch. 10. For a discussion of how upstream patents impede
biomedical research and development, see Rai and Eisenberg, “Bayh-Dole Reform and the Progress of Biomedicine.”

20 For example: “the patent system is the only proven system to bring new medicines to society on a large scale basis and in a timely manner” (www.pfizer.com/pfizer/subsites/corporate_citizenship/report/good_business.jsp).


23 Ibid.

24 This kind of relentless pressure goes a long way toward explaining why poor countries rarely dare issue a compulsory licence for a patented medicine, despite the fact that such compulsory licences are theoretically permissible pursuant to paragraph 6 of the 2001 Doha Declaration. In November 2006 and January 2007, Thailand issued compulsory licenses for HIV/AIDS drugs *Efavirenz* (Merck) and Kaletra (Abbott), and blood-thinner Plavix (Bristol-Myers Squibb and Sanofi-Aventis), and immediately came under pressure from the US government. To get a sense of how such pressure is exerted, see Congressman Jim McDermott’s speech (June 20, 2006) “A Morality Tale on AIDS” (www.house.gov/mcdermott/sp060619.shtml) and the press release (January 8, 2007) of the Office of the US Trade Representative, entitled “Schwab Announces Results of Chile IPR Review, Cites Deteriorating Performance” (www.ustr.gov/Document_Library/Press_Releases/2007/Section_Index.html).


26 This compares to about $100 billion the poor countries receive annually (2005) in official development assistance (www.oecd.org/dataoecd/52/18/37790990.pdf).

27 AIDS drugs and second-line TB medicines are prominent examples.

28 “Only 10 percent of global health research is devoted to conditions that account for 90 percent of the global disease burden” (DNDWG, *Fatal Imbalance*, p. 10; cf. GFHR, *The 10/90 Report on Health Research 2003-2004*). This imbalance may have been reduced, notably through spending by the Gates Foundation.


This point may be controversial to some extent. It has been asserted that pharmaceutical companies wildly overstate their financial and intellectual contributions to drug development and that most basic research is funded by governments and universities and then made available to the pharmaceutical industry for free. See Angell, The Truth about the Drug Companies, ch. 3; Consumer Project on Technology (www.cptech.org/ip/health/econ/rndcosts.html); UNDP, Report 2001, ch. 5. See also the GAO report (cited in n. 7) documenting the significantly reduced productivity of biomedical R&D in the pharmaceutical industry: a 147-percent rise in industry-reported R&D (from $16 billion in 1993 to $40 billion in 2004, inflation-adjusted) produced only a 38-percent increase in new drug applications (NDAs) submitted to the Food and Drug Administration, and an even smaller 7-percent rise in new molecular entities (NMEs). In particular, “from 1993 through 1995, the number of NDAs submitted for NMEs increased, but declined by 40 percent between 1995 and 2004” (p. 4). Only 12 percent of all NDAs submitted for 1993-2004 were Priority NMEs (p. 17), that is, NMEs providing a significant therapeutic benefit over existing medications.

The patent holder can also sell others a license to produce its invention. Paying a hefty licensing fee to the inventor firm, the producer must then charge a price well above, often very far above, its long-run marginal cost of production. In this case, too, the second market failure I go on to discuss in the text arises, though it does so somewhat differently.

See www4.law.cornell.edu/uscode/28/1498.html. This right has been litigated in various important cases, producing licensing fees as low as one percent in the case of the Williams patent held by Hughes Aircraft Corporation (for details, see www.cptech.org/ip/health/cl/us-1498.html).

See Kanavos et al., “The Economic Impact of Pharmaceutical Parallel Trade in European Union Member States.”

The sum of the expected costs: $52m · 25% + $35m · 60% + $40m · 15%.

Because the probability of winning this reward is estimated at 25 percent, the expected value of this reward is $160m · 25% = $40m. Companies are properly sensitive to when specific expenses or reward payments occur. So we may think of the $-figures in the text as discounted to present value by the company’s internal discount rate.

Of course, 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 the corresponding pull program.

See especially Kremer and Glennerster, Strong Medicine.

This informational deficit — though not all the other problems with prizes — can be overcome through a tender system where companies and other capable agencies would name their own prize for a specified innovation. The planners would publish the specifics of the medicine they wish to have invented, and capable organizations would then place competing “bids,” specifying the prize they 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.

For an excellent discussion of this problem, see Hollis: “Incentive Mechanisms for Innovation,” 14-15.
Advance purchase commitments could be designed to get around this problem. The promise to buy a fixed quantity of a new medicine at a high pre-set price would here be made conditional on this many doses actually being administered to patients. If fewer doses of the drug are consumed, then fewer are paid for. But this formulation of an advance purchase commitment involves a new disadvantage: incentives toward overuse of the medicine in question. If (as in one of Kremer’s numerical examples) the inventor is paid an additional $14 for each dose, up to 200 million doses, for which it finds a buyer willing to pay $1, then the inventor has powerful incentives to induce or entice buyers regardless of whether they need the medicine or not.

Because we are so used to the idea that patents confer monopoly pricing powers, my use of the word may seem out of place here. But it accords with the traditional meaning of “patent” (from the French, letters patent) as a document conferring some privilege, right, office, title, or property.


Cf. Selgelid, “Ethics and Drug Resistance.”

This opposition was displayed most dramatically when a coalition of 39 pharmaceutical companies went to court in South Africa in order to prevent their inventions from being reproduced by local generic producers and sold cheaply to desperate patients whose life depended on such affordable access to these retroviral drugs. In April 2001, the attempted law suit collapsed under a barrage of worldwide public criticism (see Barnard, “In the High Court of South Africa”). A somewhat similar suit is currently (January 2007) being brought in the Indian High Court by the Swiss pharmaceutical company Novartis against the Indian government, arguing that the Indian Patents Act is violating international trade law by being insufficiently protective of intellectual property rights. Should the suit succeed, the delivery of Indian generic medicines to Indian citizens and to people in many other poor countries will be further curtailed.

These new incentives may not, initially at least, be strong enough to stimulate research into rare (“orphan”) diseases, even when the health impact per patient promises to be large.

This short-term effect may be mitigated by the fact that the pharmaceutical industry is currently going through a slow period, caused by patent expirations on its blockbuster drugs, low productivity of its R&D, tightened regulation of its anti-competitive practices, and increased pressure from large drug purchasers. Pfizer, for instance, is planning to eliminate 10,000 positions by the end of 2008 and to reduce its European field force by more than 20 percent (mediaroom.pfizer.com/index.php?s=press_releases&item=142).

My rough estimate assumes that, under the reformed rules, the pharmaceutical industry would, at least initially, spend on research toward developing new essential drugs (especially for heretofore neglected diseases) an additional 30 to 60 percent of what it is now spending on all pharmaceutical research (cf. Moses et al. and Research!America, both cited in n. 13, and GFHR, The 10/90 Report on Health Research 2003-2004, p. 112). I also assume that the rewards offered under the reformed rules must not merely match, but greatly exceed these projected expenditures, because pharmaceutical companies will brave the risks and uncertainties of an expensive and protracted research effort only if its expected return substantially exceeds its cost. The figure in the text is a peak estimate. Expenditures under the plan would rise over the first few years as new medicines for heretofore neglected diseases become ready for delivery to patients. And expenditures would fall off again in two or three decades with declines in the remaining burden of disease.

Formulated by André Briend, Plumpy’Nut is a tasty high-protein paste. Because it can be cheaply manufactured in poor countries, keeps in an air-tight wrapper for two years without refrigeration, and does not require mixing with (often contaminated) local water, it is highly effective against malnutrition, especially in children.

One sign of interest from at least a substantial number of governments is Resolution 24 — *Public Health, Innovation, Essential Health Research and Intellectual Property Rights: towards a Global Strategy and Plan of Action* — adopted at the 59th World Health Assembly in May 2006 (WHA 59.24 — www.who.int/gb/ebwha/pdf_files/WHA59/A59_R24-en.pdf). Pursuant to this resolution, submissions from experts were solicited (www.who.int/public_hearing_phi/summary/en) and an Intergovernmental Working Group on Public Health, Innovation and Intellectual Property was convened in Geneva.

Subjunctive causes are relevant, for example, in the allocation of life years lost. We cannot ascribe all the years of life a person lost to the cause of her premature death if her environment exposed her to other such causes that would have killed her with a certain probability had she not succumbed to her actual cause of death.

It is worth noting that patent-2 does exceptionally well in terms of avoiding costly litigation. The existing regime generates a lot of litigation involving generic companies who have strong incentives to challenge the patent-1 of any successful medicine. Generic companies have no incentive to challenge a patent-2, because they are free to replicate the medicine even without such a challenge. The patent-2 regime does no better in regard to rivalrous claims to inventorship. But these constitute only a small fraction of present litigation expenses. I am grateful to Rochelle Dreyfuss for valuable discussion of this point.

This brings out a second significance of the word “full.” It signifies not only that medicines are to be pulled all the way to patients, to make them effective in reducing mortality and morbidity. It can also signify that such incentives might ultimately be targeted on all the severe deprivations that constitute the world poverty problem.

For some evidence that citizens of affluent countries are willing to be taxed to support pharmaceutical research and other initiatives towards improving global health, see Woolley, Propst, and Connelly, “United States Investment in Global Health Research,” pp. 93-4.