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 (note 136). Hundreds of millions more suffer grievously from these diseases. The lives of additional hundreds of millions are shattered by severe illnesses or premature deaths in their family. And 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 the ill health of their members.

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 health — and, within these categories, women and girls in particular. The most significant causal factor determining this distribution is poverty: Nearly all the avoidable mortality and morbidity occurs in the poor countries and among their poorer inhabitants in particular.

There are different ways of attacking this problem through global institutional reforms. One approach, explored in chapters 5-8, focuses on the eradication of severe poverty. As we have seen, relatively minor and realistically attainable institutional reforms — causing a modification of the global income distribution involving no more than one percent of the global product — would suffice to end severe poverty worldwide. The bottom half of the human population would still live on merely 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 in malaria infested regions, 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 global burden of disease (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.\textsuperscript{343} Still, this wider recognition does not easily translate into political reform. Some believe, like Winston Churchill about democracy, that the present regime is the lesser evil in comparison to its alternatives that have any chance of implementation. Others, more friendly to reform, disagree about what the flaws of the present system are exactly and have put forward a wide 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 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 is destined to remain a philosopher’s pipe dream. More particularly: 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 parliaments and international organizations such as the WTO and WHO. But ultimately, these decision makers are accountable to the world’s people who in turn bear ultimate responsibility for their decisions. It is a widely shared responsibility and urgent task to explore and assess the more promising reform options toward reducing the vast disease burden produced and reproduced by current institutional arrangements.

\textbf{9.1 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 \textit{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\textsuperscript{344} and also discourage, impede, and delay the manufacture of generic medicines in many other ways — through provisions on data exclusivity,\textsuperscript{345} for instance, and through restrictions on and political pressures against the effective use of compulsory licences.

Intellectual property rights can help ensure that creative productions 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 monopoly patents that prohibit the unlicensed reproduction of a vast range of products and productive processes. Such patent protections are more problematic, morally, than copyrights, especially when they confer property rights in biological organisms (such as seeds of plants used for food), in medically useful
molecules, or in pharmaceutical research tools needed to develop new medicines. Patents of these kinds are morally problematic insofar as they, directly or indirectly, impede the global poor’s access 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 they are, as economists say, non-rivalrous: 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 to physical reproduction is entirely cost-free.

Yet, the driving idea of the grand intellectual property rights initiative of recent years 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.

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.

What could possibly justify 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 four serious difficulties. First, even on the most property-friendly accounts of rights it is puzzling why the innovative creation of a physical object should earn the innovator property rights not merely in this object token but in all objects of its type. Nozick specifically insists that a medical researcher is entitled to withhold a medicine he invented even from those who need it to survive. He defends this claim by 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. In endorsing this Lockean 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.” 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 they legitimately own. On the contrary: Nozick’s line of thought requires that others be left free to replicate. For if the researcher’s activity — acquiring chemicals and combining them into a medicine — did preclude others from doing likewise, then his activity would worsen the situation of others by blocking an opportunity they had before he acted. To be sure, Nozick’s view leaves the researcher
free to keep his knowledge and medicine entirely to himself, even if millions die as a result, and free also to sell his medicine only to those who contractually promise not to allow it to be analyzed or reproduced. But he has no veto powers over third parties who synthesize medicine of the same type independently — 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, rights-based (libertarian and deontological) theorizing actually refutes 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 do not leave enough and as good to others, thus violating the Lockean proviso.

Second, it is hard to see why such a natural right of inventors should apply to pharmaceutical firms whose products rely so heavily on basic research conducted at universities and public institutions with funds supplied by governments and tax-advantaged foundations. Third, it is hard to explain why such a natural right of inventors should have precisely the contours enshrined in the TRIPS and TRIPS-plus agreements: 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 enshrined in law? Why should this natural right prohibit unlicensed use of an idea by someone who invents it independently? The fourth difficulty, finally, is that of showing that this natural right of inventors is so weighty that even the right to life of poor patients must be curtailed to accommodate it, rather than the other way around.

9.2 The argument from social utility

The difficulties of defending intellectual property rights by appeal to natural rights are so overwhelming that most defenders of the ongoing intellectual property initiative appeal instead to the social utility 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 social utility cannot be dismissed.

To assess this argument, we need to ask: how does the global intellectual property regime now taking shape affect social utility by raising or reducing 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 social-utility argument for the current regime cannot succeed by showing merely that it is preferable to the complete absence of intellectual property rights anywhere. Second, the social-utility argument for the ongoing intellectual property initiative fails if the decline in social utility it brings for poor populations (by reducing their access to patented seeds and pharmaceuticals) is greater than the increase in social utility it brings to rich populations (by enhancing corporate income from monopoly patents and by accelerating the development of new seeds and pharmaceuticals). On any plausible conception of social utility, which gives equal weight to the well-being of rich and poor human beings alike, 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. 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 unlicensed cheaper versions of its medicine and can thereby increase 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 (and 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 reorienting themselves toward serving patients in wealthier countries by researching and developing innovative medicines for the ailments of the affluent.

These 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 greatly 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 the 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 equal weight to the vital interests of rich and poor alike — the recent tightening of the intellectual property regime must be judged disastrous in social-utility terms. 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 poor 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 reason is that medicines whose development is incentivized or accelerated by the new rules will eventually go off-patent and will often then become available to the poor 20 or 25 years in the future (sooner than would otherwise be the case). This response is difficult to articulate in the face of millions of people whose survival or health now depends on access to these medicines. Yet, it contains a real insight that points us beyond the two regimes we have considered in this section: the emerging TRIPS and TRIPS-plus regime and its more differentiated predecessor. The next section will return 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 surely they are 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 50 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 enabling them to buy arms, 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 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 conception of social utility, 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 the monopolist price, typically vastly higher than the marginal cost of
production.361

9.3 Toward a better way of stimulating research and development of essential medicines

Imagine for a moment that we really cared about social utility understood in a way that gives equal
weight to the basic interests of all human beings regardless of their income. If so, we would certainly
want the intellectual achievements embedded in life-saving seeds and medicines to be freely
available in poor countries. 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 sanitation, to minimally adequate clothing and shelter, to adequate sleep and rest, and to
minimal health-related knowledge and advice. And little is done to control environmental hazards
(such as malaria-carrying mosquitoes, 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, pimples, and erectile dysfunction 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 process. 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, to have bad side effects, or is denied government approval for some other reason. 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 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 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 provide 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 be expected to provide them. It may be appropriate in certain contexts to take as a given the existing patent regime and the high prices it engenders. But in the very 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 but silly objection that monopoly prices barely impede access to essential drugs as listed by the WHO.

9.4 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 proprietary drugs to different customers at different prices, thereby realizing a large profit margin from sales to the more affluent without renouncing 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 (but see note 358).

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 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, $25 in Mexico and $300 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 effective in the case of pharmaceutical products which are small and lightweight 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 are then likely to find their (in any case insubstantial) gains greatly outweighed by profits foregone in rich-country markets due to diversion. Anticipating such a net loss, 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 marginal cost of production are excluded from this drug because they cannot afford the much higher monopoly price.
To be sure, insofar as a government succeeds, against heavy pressure from pharmaceutical companies and often their governments, in exercising its right to issue compulsory licenses, 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, differential pricing solutions can help give the poor access to a medicine at competitive market prices only if there is enough market demand for this medicine also among the affluent who, by being willing to purchase the medicine at monopoly prices, make an investment in its development profitable. Most diseases that very rarely strike the affluent and are therefore neglected under the current regime would continue to be neglected under differential pricing: The slight profits obtainable by selling to the poor at prices they can afford minus profits lost through seepage would rarely suffice to tip the scales in favor of undertaking a costly research and development effort.

9.5 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 drug are to be provided as a public good that all pharmaceutical companies may use free of charge. This reform would eliminate the second market failure (associated with monopoly pricing powers) by allowing competition to bring the prices of new essential drugs down close to their 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 like the rules of the current TRIPS regime are. The first reform component is then that intellectual results of successful efforts to develop new essential drugs are to be provided as public goods that all pharmaceutical companies anywhere may use free of charge.

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.

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 an arithmetically normal 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 $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 the reward is considerably greater than $160 million. In this example, an effective pull program would have to offer a reward of 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. 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 combined with push programs or 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 prize funds that underwrite fixed rewards for the innovator who first produces a medicine that meets certain specific desiderata. The reward is typically specified 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 prize funds 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, prize funds have three serious drawbacks. First, politicians, bureaucrats and experts play a substantial role by deciding which diseases ought to researched, how to specify the remedy to be aimed for, and how large a reward should be offered for a remedy meeting these specifications. By effectively determining which research will be undertaken, 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 stimulate the most cost-effective innovations. But their own incentives to try hard to incentivize the most cost-effective innovations 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.\textsuperscript{374} Given weak incentives and poor information, the planners’ focusing of prize incentives would likely be seriously suboptimal.

Another draw-back of prize funds 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 actual access to it (cf. note 376). This thought shows that prize funds are not really a pull solution in the full sense. They use prizes to 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.

The third draw-back of prize funds is that they work in a haphazard manner. Specific diseases and types of intervention are picked and a prize competition organized around them, but other diseases and types of intervention are ignored and sidelined. Such case-by-case decision making tends to lead to erratic funding as governments and other funders, when encountering budget problems, are likely to skip or to postpone a planned prize competition.

\textit{9.6 A full-pull plan for the provision of pharmaceuticals}

Let me introduce the essentials of a pull program that overcomes these three difficulties. The basic idea is that, similar to the current regime, innovators are entitled to take out a multi-year patent on any essential medicine they invent, but, during the life of the patent, are rewarded, out of public funds, in proportion to the impact of their invention on the GBD.\textsuperscript{375} This idea avoids the first draw-back of prize funds 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, but incentivized instead each to undertake whatever research program 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 wisdom of political planners. A full pull scheme replaces a central-planning solution with a competitive-market solution.

A full pull scheme avoids the second draw-back of prize funds 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 that 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:

\begin{itemize}
\item Any inventor firm would have incentives to sell its innovative medicines cheaply, perhaps \textit{below} their marginal cost of production, in order to make them affordable to even very poor people who need them. In addition, such a firm would have reason to encourage, support, and 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 further increase affordability and availability and therefore multiply the number of users and hence the invention’s favorable impact on the GBD. Lower prices for advanced medicines benefit poor and affluent alike by reducing what they pay for drugs, insurance, and/or their national health system.
\item 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).
\item 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 prize funds 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). — Rather than ignore poor countries as unprofitable 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 fund 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 fund regime, any effort by innovators to enhance the health impact of their rewarded inventions constitutes a loss to their bottom line.

A full pull scheme avoids the third drawback of prize funds 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 would be driven by how their work affects human health worldwide.

Better than prize funds, 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 marginal cost of production. A full-pull scheme overcomes this defect most decisively for currently neglected diseases that are severe and widespread (cf. notes 363-5). 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.

One might worry that such new rewards would also reduce incentives to develop medicines for diseases that, though they add little to the GBD (on any plausible conception thereof), affluent patients are willing to pay a lot 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 profitable opportunities to develop non-essential drugs for even more profitable new opportunities to develop essential drugs. But the biotech and pharmaceutical industries will also attract new capital and add research capacity in order to take advantage of all profit opportunities that are lucrative (relative to investment opportunities available in other industries).

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 reform 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 biotech 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 variant of the public-good strategy is then the creation of a second type of pharmaceutical patent that rewards inventors not with monopoly pricing powers but in proportion to the invention’s impact on the GBD. Under the reformed patent regime, any inventor firm is free to choose either the conventional monopoly patent (“patent-1”) or the new patent-2. If it chooses the latter, the patented knowledge is treated as a public good, making the new medicine available for generic production worldwide.

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.\textsuperscript{381} 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 solid 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 against disease-carrying animals (such as mosquito nets), off-patent medicines, and many more. Why should we reward only new pharmaceutical remedies when there are alternative, 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. 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 against disease-carrying animals (such as mosquito nets), off-patent medicines, and many more. Why should we reward only new pharmaceutical remedies when there are alternative, 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 trying to separate them out as unrewardable. 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 biotechnology and pharmaceutical 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 effectively used to avert harm from affluent populations who can pay for it. But the current patent regime gives innovators no incentive to reduce the incidence of their target disease overall. 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 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 very 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 Malarone 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 biotech 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 behave, but in how we regulate and incentivize them. If we structure markets so that corporations can make billions by getting people to smoke, then corporations will work hard to get people to smoke. If we structure markets so that corporations can make 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 directed against the great diseases that bring so much misery and premature death to poor people everywhere. It would be greatly to underestimate these powers of free enterprise to presume that pharmaceutical 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 one of their 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 — made substantially more likely by the way it fits the interests of the biotechnology and pharmaceutical industries — would provide an impetus for further reform.

9.7 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-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 biotech/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.

In the world as it is, the idea of spending tens of billions of dollars annually 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 of dollars 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.
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. There is little each pharmaceutical company can do on its own to avoid these complaints. These companies compete against one another, and any company acting “nicely” in more than marginal ways would lose ground against the others. The pharmaceutical companies are locked into a prisoners’ dilemma where conduct that is best for each is worse for all of them. Moreover, their incentivized conduct is not only worse for them, it is also much worse for the rest of the world: These companies are not merely doing worse than they might in terms of reputation and profits, but are also complicit in tens of millions of premature deaths and unimaginable human misery.

While pharmaceutical companies cannot solve this problem individually, under the existing rules, they can 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 view 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 deliberations about reform 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 medicines for serious diseases — not those for minor ailments or blemishes, not 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 status quo intolerable unite behind a common reform plan that clearly recognizes and accepts the limited focus on essential medicines. A reform amendment 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. We must convince ordinary citizens to support the plan even though it requires public funds, and we must convince more-radical reformers (prominent in many health-related NGOs) to support the plan even though it does not hurt the pharmaceutical industry.

Leaving ordinary citizens to the next section, let me conclude this one 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. 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. 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 industry. 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 does the pharmaceutical industry, for the additional reason of maximizing its profits. Since these companies negotiate under a virtual veil of ignorance with respect to as yet uninvented medicines and their inventors, 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 reduce litigation expenses. 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.

9.8 Justifying the plan to affluent citizens and their representatives

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 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 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 much 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 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 overall profit by serving a much larger patient population. (Insofar as pharmaceutical innovators would be uncertain about which patent would yield greater profits, they 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 recent medical advances 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 sort of 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 example, because, even if they could develop effective medicines, they would not be able to make much money from selling or licensing them. Under the alternative regime I suggest we design, inventor firms could make lots of money 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 most 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 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.385

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.

9.9 The reform as mandated by human rights

A particular scheme of rules for incentivizing pharmaceutical innovation has been imposed upon 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 among the poor of the target diseases. 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 increasing the profit opportunities of biotechnology and pharmaceutical companies and by imposing at most a small loss (relative to the existing scheme) on the healthiest and most affluent segments of the human population.

The central claims of this book are that any institutional order is unjust if its imposition foreseeably produces an avoidable massive human rights deficit, and that the existing global institutional order is severely unjust by this standard. Many believe that the vast poverty-related harms we witness are causally unrelated to our global institutional order or at least cannot be substantially reduced through feasible reforms. I have tried to refute this belief by discussing in some detail three mutually independent minor reforms of the global institutional order that would each dramatically reduce existing poverty-related human misery. The three cases can memorably be named the “three P’s”: Protectionism, Privileges, and Pharmaceuticals.
The present trading rules permit the affluent countries to use tariffs, quotas, anti-dumping duties, export credits and subsidies to protect their markets against cheap imports of goods and services from poor countries. It is widely accepted that these uncompensated trade barriers greatly reduce incomes and employment among the poor in less developed countries. Given the global incidence of severe poverty and of poverty-related diseases and deaths, it is undeniable that these trade barriers contribute substantially to the underfulfillment of human rights worldwide.

Many less developed countries are ruled by corrupt and repressive rulers whose policies bring great misery to their populations. Most of these tyrants and juntas could not maintain their horrendous misrule without foreign support. Of central importance here is an institutionalized global practice of recognition that in effect authorizes any person or group holding effective power in a country — regardless of how they acquired or exercise it — 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 is of great advantage to Western countries, especially in regard to their resource needs. But it greatly contributes to the incidence of repression, violence, and severe poverty in the less developed countries.

Feasible global institutional reforms toward the dismantling of protectionist barriers and of the international privileges could greatly reduce the incidence of severe poverty and hence of poverty-related mortality and morbidity, or so I have argued in previous chapters. The present chapter has shown that many of these 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 impact on the GBD rather than through monopoly rents. This reform would bring prices of patented drugs worldwide close to their marginal cost of production and would powerfully stimulate pharmaceutical research into currently neglected diseases concentrated among the poor. Its feasibility shows that the existing pharmaceutical-patent regime (TRIPS as aggravated by bilateral agreements) is severely unjust — and its imposition a human rights violation on account of the avoidable mortality and morbidity it foreseeably produces.

With this background, we can look once more at the question why we more privileged citizens of affluent countries should support a reform of the global health system — or of the WTO trading rules or of the international privileges — that reduces harms suffered by poor people in the less developed countries. The landholders of feudal France or Russia could have asked likewise. And the answers are closely analogous: Even if such reforms involve opportunity costs for us, we ought to support them insofar as they are necessary for rendering minimally just (in the explicated sense of “realizing human rights insofar as this is reasonably possible”) the rules of the world economy considered as one scheme. Justice in this very 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. However, minimal justice is not compatible with these rules being designed so that they foreseeably result in a much higher incidence of severe poverty and in much higher 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.


Chapter 9  Intellectual Property Rights and Access to Essential Medicines

339  Such morbidity is due to the conditions listed in note 136 as well as to 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.


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


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

344  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 ask for an automatic 30-month stay and, beyond that, threaten or initiate legal action that, regardless of its merit, can delay commencement of generic production by several years or even deter generic production altogether. 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 Pattern 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.”

345  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.

346  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.”

347  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.”


349  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, and section 5.3 above.

350  It is instructive to work through these same moves with a more homely example, such as the discovery that certain dishes can be made to taste better by adding mushrooms. It is absurd to think
that, if I am the first to make this discover and you observe me picking mushrooms and guess at my secret, you would do wrong to add mushrooms to your dishes without my permission. 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.”

This pattern emerged in the US after Congress, in 1980, 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, 7-8, 22-27, 56-76.

See also Sterckx, “The Ethics of Patenting,” for more elaborate objections to the natural-right account of intellectual property.

See the GAO and FTC studies cited in note 343; also Goozner, The $800 Million Pill, ch. 8, and Angell, The Truth about the Drug Companies, ch. 10.

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).


White Man’s Shame. The Economist, September 25, 1999, p. 89.

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. Thailand issued a compulsory license for Merck’s HIV/AIDS drug Efavirenz on November 29, 2006, and immediately came under pressure from the US government. For accounts 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 7, 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).

See, for example, the speech “Cutting Agricultural Subsidies” by former World Bank Chief Economist Nick Stern (www.globalenvision.org/library/6/309).

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

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

“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.

GFHR, The 10/90 Report on Health Research 2003-2004, p. 122. There are somewhat different ways of calculating the GBD, and I am not committed to any particular way.

Trouiller et al., “Drugs for Neglected Diseases”; DNDWG, Fatal Imbalance.
Chirac and Toreelle, “Global Framework on Essential Health R&D.”

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 note 343) 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 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.

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 prize funds — 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 issue the specifics of the medicine they would like 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.

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 31 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.

379 These new incentives may not, initially at least, be strong enough to stimulate research into (“orphan”) diseases that are severe but rare.

380 This short-term problem may be mitigated by the fact that the pharmaceutical industry is currently going through a slow period. Pfizer, for instance, is planning to lay off 10,000 workers in 2007.

381 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. 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.


384 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.

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