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Incentives for pharmaceutical research: must they exclude the poor from advanced medicines?*

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Introduction

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 (IPRs) into the fabric of the global trading system. This initiative included the *Trade-Related Aspects of Intellectual Property Rights* (TRIPS) Agreement formulated in the so-called Uruguay Round that led up to the formation of the World Trade Organization (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 market exclusivity beyond the twenty years enshrined in the TRIPS Agreement[1] and also discourage, impede, and delay the manufacture of generic medicines in many other ways, e.g. through provisions on data exclusivity[2] and through restrictions on the effective use of compulsory licences.

Intellectual Property Rights (IPRs) can help ensure that creative productions are protected from unauthorized modification and that their authors receive royalties or licensing income from the reproduction

Many thanks to Aidan Hollis and Matt Peterson for their helpful comments and suggestions.

[1] 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 additional patents outlast the primary patent. In some countries, such as the US and Canada, these supplementary patents 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 threaten or initiate legal action that, though it has no chance of ultimate success, can delay commencement of generic production by several years or even deter generic production altogether. See NIHCM Foundation, Changing Pattern of Pharmaceutical Innovation, 2002, available at: www.nihcm.org.

[2] See www.accessmed-msf.org/documents/Data%20exclusivity%20May%2004.pdf.

of their work. Much more consequential than such copyrights, however, are patents, which prohibit the unauthorized 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 used in food production), in molecules that make medicines effective, or in pharmaceutical research tools needed to develop new pharmaceuticals.[3] The present essay analyses the severe moral problems the current regime engenders in the domain of pharmaceuticals. It also proposes a complement to the existing rules – the Health Impact Fund – that would substantially mitigate these problems.

Essential medicines and patents

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

With medicines, the fixed cost of developing a new product is extremely high for two reasons. It is very expensive to research and fine-tune a new medicine and then to take it through elaborate clinical trials and national approval processes. Moreover, most promising research ideas fail somewhere along the way and thus never lead to a marketable product. Both reasons combine to raise the research and development cost per new marketable medicine to somewhere around half a billion dollars or more. Commencing manufacture of a new medicine once it has been invented and approved is cheap by comparison. Because of this fixed-cost imbalance, pharmaceutical innovation is not sustainable in a

[3] 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). For details, see Arti K. Rai and Rebecca S. Eisenberg "Bayh–Dole Reform and the Progress of Biomedicine," *Law & Contemporary Problems* 66, 1 (2003), pp. 289–314 (also available at: www.law.duke.edu/journals/66LCPRai).

free market system: competition among manufacturers would quickly drive down the price of a new medicine to near its long-term marginal cost of production, and the innovator would get nowhere near recovering its investment.

The conventional way of correcting this market failure of undersupply is to reward innovators with patents that entitle them to forbid others to produce or distribute the innovative product and to waive this entitlement in exchange for a licensing fee. The result of such market exclusivity is an artificially elevated sales price that, on average, enables innovators to recoup their initial investment through selling products that, even at prices far above marginal cost, are in high demand.

Monopolies are widely denounced by economists as inefficient and by ethicists as an immoral interference in people's freedom to produce and exchange. In regard to patents, however, many believe that the curtailment of individual freedom can be justified by the benefit, provided patents are carefully designed. One important design feature is that patents confer only temporary market exclusivity. Once the patent expires, competitors can freely enter the market with copies of the original innovation and consumers need thus no longer pay a large mark-up over the competitive market price. Temporal limits make sense, because additional years of patent life barely strengthen innovation incentives: At a typical industry discount rate of eleven per cent per annum,[4] a ten-year effective patent life generates sixty-eight per cent, and a fifteen-year effective patent life eighty-two per cent, of the profit (discounted to present value) that a permanent patent would generate.[5] It makes no sense to impose monopoly prices on all future generations for the sake of so slight a gain in innovation incentives.

During the life of the patent, everyone is legally deprived of the freedom to produce, sell, and buy a patented medicine without permission from the patent holder. This restraint hurts generic producers and it

[4] Joseph A. DiMasi, Ronald W. Hansen, and Henry G. Grabowski, "The Price of Innovation: New Estimates of Drug Development Costs," *Journal of Health Economics* 22 (2003), pp. 151–85.

[5] Patent life is counted from the time the patent application is filed. Effective patent life is the time from receiving market clearance to the time the patent expires. My calculation in the text assumes constant nominal profit each year. In reality, annual profit may rise (due to increasing market penetration or population growth) or fall (through reduced incidence of the disease or through competition from "me-too drugs" developed by competing firms). For most drugs, sales decline after they have been on the market for six years or so, and this strengthens the reasons for limiting patent life. My reasoning assumes that future health benefits are not to be discounted.

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

IPRs and essential medicines for the world's poor

Patents are morally problematic insofar as they directly or indirectly impede access by the global poor to basic foodstuffs and essential medicines. The urgency of this concern can be gauged by examining the present condition of the global poor. Today, one-third of all human deaths are from poverty-related causes: 50,000 each day or 18 million every year,[6] including 9.2 million children under the age of five.[7] Hundreds of millions more suffer grievously from treatable medical conditions; and the lives of even more people are shattered by severe illnesses or premature deaths in their family. Living with such severe deprivations, poor people are bound to be susceptible and vulnerable to infectious diseases and often unable to overcome them. Health problems of epidemic proportions weigh down the economies of poor countries and regions, thereby perpetuating their poverty which in turn contributes to the ill health of their populations.

Severe deprivation has always been the fate of a large segment of humankind – in slaveholding societies, under feudalism, and in the colonial period. These past deprivations were associated with what we now understand to have been grievous injustices. We must suspect that existing massive deprivations are also associated with similarly grievous social injustices today, when humankind has become so affluent in aggregate that such massive deprivations are clearly avoidable. With 15.7 per cent of the world population, the high-income OECD countries control 79 per cent of the global product, while the aggregate income of the poorer half of humankind is well below 2 per cent. While many of these poor live on somewhere around $100 or $200 per person per year, the annual *per capita* social product is $7,958 for the world at large and $37,566 for the high-income countries.[8]

[6] World Health Organization, *The Global Burden of Disease: 2004 Update* (Geneva: WHO Publications, 2008 and available at: www.who.int/healthinfo/global_burden_disease/2004_report_update/en/index.html).

[7] Roshni Karwal, "Policy advocacy and partnerships for children's rights" (2008), available at: www.unicef.org/policyanalysis/index_45740.html.

[8] World Bank, *World Development Report 2009* (Washington, DC: The World Bank, 2009), p. 353.

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.[9] 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.

My assessment of the intellectual property regime and its possible modifications is guided by the cosmopolitan principle that the health, well-being, and longevity of each human being is of equal value.[10] It is a wonderful thing about the products of thought that they are, as economists say, non-rivalros: 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 achievements do have a cost that rises – typically at a decreasing rate – as additional copies are made. But such physical reproduction begins only after the creative intellectual labors are complete. Physical reproduction adds nothing to these intellectual labors; and these intellectual labors add nothing to the marginal cost of physical reproduction. The creative intellectual ingredient to physical reproduction is entirely cost-free. Yet, the driving idea of the grand IPR initiative of recent years is that any benefit derived from any such intellectual achievement, by any person, anywhere, must be paid for, and that any unpaid-for benefit

[9] David Barnard, "In the High Court of South Africa, Case No. 4138: The Global Politics of Access to Low-Cost AIDS Drugs in Poor Countries," *Kennedy Institute of Ethics Journal* 12 (2002), pp. 159–74.

[10] Thomas Pogge, "Cosmopolitanism" in *A Companion to Contemporary Political Philosophy*, ed. Robert E. Goodin, Philip Pettit, and Thomas Pogge (Oxford: Blackwell, 2007), pp. 316–31.

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.

The argument from natural rights

Before 2005, Indian law allowed only patents on processes, none on products. As a result, India had a thriving generic pharmaceuticals industry that cheaply supplied copies of patented medicines for poor patients throughout the world's poor regions.

> But when India signed the TRIPS agreement in 1994, it was required to institute patents on products by Jan. 1, 2005. These rules have little to do with free trade and more to do with the lobbying power of the American and European pharmaceutical industries. India's government has issued rules that will effectively end the copycat industry for newer drugs. For the world's poor, this will be a double hit – cutting off the supply of affordable medicines and removing the generic competition that drives down the cost of brand-name drugs.[11]

What could possibly justify blocking the supply of life-saving medicines from Indian manufacturers to the world's poorest populations? In response, one might invoke a natural right of any inventor to control the use of her invention. But this response faces four grave difficulties.[12] First, even on the most property-friendly accounts of rights — such as those of Locke and Nozick — it is puzzling why the innovative creation of a physical object should earn one property rights not merely in this object token but in all objects of its type. Why should the fact that you produced a certain molecule out of ingredients you legitimately own give you veto power of my producing a like molecule later out of ingredients that I legitimately own? Second, it is hard to see why pharmaceutical firms should qualify for such exclusive inventors' rights when so much of the basic research used in their medicines is conducted at universities and public institutions with funds supplied by governments and tax-advantaged foundations.[13] Third, it is very hard to explain why

[11] Editorial, "India's Choice," *The New York Times*, January 18, 2005.

[12] See also Aidan Hollis and Thomas Pogge, *The Health Impact Fund: Making New Medicines Accessible for All* (Incentives for Global Health, 2008), pp. 62–68. The book is freely available at: www.healthimpactfund.org.

[13] This pattern emerged in the US after Congress, in 1980, passed the Bayh–Dole Act which allows pharmaceutical companies, professors, and clinicians to cash in on patented

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 protected by patents (or copyrights or trademarks)? Why should this natural right entitle inventors to market exclusivity for precisely twenty years? And, most perplexing, why should this natural right prohibit unauthorized use of the idea by someone who invents it independently? Fourth, it must also be shown 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.

The argument from social utility

The difficulties of defending IPRs as natural rights are so overwhelming that most defenders of the ongoing IPR initiative appeal instead to the social utility of protecting property rights in intellectual achievements: such rights incentivize intellectual innovation, or so we are told. The experience of recent years suggests that IPRs 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.[14] Yet, IPRs also 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 IPR regime now taking shape affect social utility by raising or reducing the well-being of diverse human populations? We can formulate a number of drawbacks of this regime.

High prices. While a medicine is under patent, it will be sold near the profit-maximizing monopoly price which is largely determined by

applications of basic research done at universities or at the National Institutes of Health. For a brief account with further references, see note 3, Rai and Eisenberg 2003. See also Marcia Angell, "The Truth about the Drug Companies," *The New York Review of Books* 51, 12 (2004), pp. 52–58 (also available at: www.nybooks.com/articles/17244); Donald Light, "Basic Research Funds to Discover New Drugs: Who Contributes How Much?" in *Monitoring Financial Flows for Health Research 2005: Behind the Global Numbers* ed. Mary Anne Burke and Andrés de Francisco, (Geneva: Global Forum for Health Research, 2006), pp. 29–46.

[14] Merrill Goozner *The $800 Million Pill: The Truth Behind the Cost of New Drugs*. (Berkeley and Los Angeles: University of California Press, 2004), ch. 8; Marcia Angell *The Truth about the Drug Companies: How They Deceive us and What to Do about It* (New York: Random House, 2004), ch. 10.

the demand curve of the affluent. When wealthy people really want a drug, then its price can be raised very high above the cost of production before increased gains from enlarging the mark-up are outweighed by losses from reduced sales volume. With patented medicines, mark-ups in excess of 1000 per cent are not exceptional.[15] When such exorbitant mark-ups are charged, only a few of the poor can have access through the charity of others.

Neglect of diseases concentrated among the poor. When innovators are rewarded with patent-protected mark-ups, diseases concentrated among the poor – no matter how widespread and severe – are not attractive targets for pharmaceutical research. This is so because the demand for such a medicine drops off very steeply as the patent holder enlarges the mark-up. There is no prospect, then, of achieving high sales volume *and* a large mark-up. Moreover, there is the further risk that a successful research effort will be greeted with loud demands to make the medicine available at marginal cost or even for free, which would force the innovator to write off its initial investment as a loss. In view of such prospects, biotechnology and pharmaceutical companies predictably prefer even the trivial ailments of the affluent, such as hair loss and acne, over tuberculosis and sleeping sickness. This problem of neglected diseases is also known as the 10/90 gap, alluding to only ten per cent of all pharmaceutical research being focused on diseases that account for ninety per cent of the global burden of disease.[16] Malaria, pneumonia, diarrhoea, and tuberculosis, which together account for twenty-one per cent of the global burden of disease, receive 0.31 per cent of all public and private funds devoted to health research.[17] And diseases confined to the tropics tend to be the most neglected: of the 1393 new medicines approved between 1975 and 1999, only thirteen were specifically indicated for tropical diseases and, of these thirteen, five were by-products of veterinary research and two had been commissioned by the military.[18] An additional three drugs were indicated

[15] In Thailand, Sanofi-Aventis sold its cardiovascular disease medicine Plavix for 70 baht ($2.20) per pill, some 6000 per cent above the price at which the Indian generic firm Emcure agreed to deliver the same medicine (Clopidogrel). See Oxfam, *Investing for Life,* Oxfam Briefing Paper, November 2007: 20, available at: www.oxfam.org/en/policy/bp109_investing_for_life_0711 (accessed 10 January 2009).

[16] Global Forum for Health Research, *The 10/90 Report on Health Research 2003–2004* (Geneva: GFHR, 2004) (also available at: www.globalforumhealth.org).

[17] *Ibid*., p. 122.

[18] Patrice Trouiller, Els Torreele, Piero Olliaro, *et al.* "Drugs for Neglected Diseases: A Failure of the Market and a Public Health Failure?," *Tropical Medicine and International*

for tuberculosis. The next five years brought 163 new drugs of which five were for tropical diseases and none for tuberculosis which together account for twelve per cent of the total disease burden.[19]

Bias toward maintenance drugs. Medicines can be sorted into three categories: curative medicines remove the disease from the patient's body; maintenance drugs improve well-being and functioning without removing the disease; preventative medicines reduce the likelihood of contracting the disease in the first place. Under the existing patent regime, maintenance drugs are by far the most profitable, with the most desirable patients being ones who are not cured and do not die (until after patent expiration). Such patients buy the medicine week after week, year after year, delivering vastly more profit than would be the case if they derived the same health benefit from a cure or vaccine. Vaccines are least lucrative because they are typically bought by governments, which can command large volume discounts. This is highly regrettable because the health benefits of vaccines tend to be exceptionally great as vaccines protect from infection or contagion not merely each vaccinated person but also their contacts. Once more, then, the present regime guides pharmaceutical research in the wrong direction – and here to the detriment of poor and affluent alike.

Wastefulness. Under the present regime, innovators must bear the cost of filing for patents in dozens of national jurisdictions and then also the cost of monitoring these jurisdictions for possible infringements of their patents. Huge amounts are spent in many jurisdictions on costly litigation that pits generic companies, with strong incentives to challenge any patent on a profitable medicine, against patent holders, whose earnings depend on their ability to defend, extend, and prolong their patent-protected mark-ups. Even greater costs are due to the deadweight loss "on the order of $200bn" that arises from blocked sales to buyers who are willing and able to pay some price between marginal cost and the much higher monopoly price.[20]

Health 6, 11 (2001), pp. 945–51; Drugs for Neglected Diseases Working Group, *Fatal Imbalance: The Crisis in Research and Development for Drugs for Neglected Diseases* (Geneva: MSF and DNDWG, 2001) (also available at: www.msf.org/source/access/2001/fatal/fatal.pdf), p. 11.

[19] Pierre Chirac and Els Toreelle, "Global Framework on Essential Health R&D," *The Lancet* 367, (2006), pp. 1560–61, also available at: www.cptech.org/ip/health/who/59wha/lancet05132006.pdf.

[20] Personal communication from Aidan Hollis, based on his rough calculation. See also Aidan Hollis, "An Efficient Reward System for Pharmaceutical Innovation" (2005:8) at http://econ.ucalgary.ca/fac-files/ah/drugprizes.pdf, where he quantifies the deadweight

Counterfeiting. Large mark-ups also encourage the illegal manufacture of fake products that are diluted, adulterated, inert, or even toxic. Such counterfeits often endanger patient health. They also contribute to the emergence of drug-specific resistance, when patients ingest too little of the active ingredient of a diluted drug to kill off the more resilient pathogenic agents. The emergence of highly drug resistant disease strains – of tuberculosis, for instance – poses dangers to us all.

Excessive marketing. When pharmaceutical companies maintain a very large mark-up, they find it rational to make extensive efforts to increase sales volume, often by scaring patients or by rewarding doctors. This produces pointless battles over market share among similar ("me-too") drugs as well as perks that induce doctors to prescribe medicines even when these are not indicated or when competing medicines are likely to do better. With a large mark-up it also pays to fund massive direct-to-consumer advertising that persuades people to take medicines they don't really need for diseases they don't really have (and sometimes for invented pseudo diseases).[21]

The last-mile problem. While the present regime provides strong incentives to sell even unneeded patented medicines to those who can pay or have insurance, it provides no incentives to ensure that poor people benefit from medicines they urgently need. Even in affluent countries, pharmaceutical companies have incentives only to sell products, not to ensure that these are actually used, properly, by patients whom they can benefit. This problem is compounded in poor countries, which often lack the infrastructure to distribute medicines as well as the medical personnel to prescribe them and to ensure their proper use. In fact, the present regime even gives pharmaceutical companies incentives to disregard the medical needs of the poor. To profit under this regime, a company needs not merely a patent on a medicine that is effective in protecting paying patients from a disease or its detrimental symptoms. It also needs this target disease to thrive and spread because, as a disease waxes or wanes, so does market demand for the remedy. A pharmaceutical company helping poor patients to benefit from its patented medicine would be undermining its own profitability in three ways: by paying for the effort to make its drug competently available to them, by

loss in the region "of $5 bn–20 bn annually for the US. Globally the deadweight loss is certain to be many times this figure, because in many markets drug insurance is unavailable and so consumers are more price-sensitive."

[21] See the special issue on disease mongering, ed. Ray Moynihan and David Henry, *PLoS Medicine* 3 (2006), pp. 425–65.

curtailing a disease on which its profits depend, and by losing affluent customers who find ways of buying, on the cheap, medicines meant for the poor.

In assessing the emerging global IPR regime it is crucial to avoid the false dichotomy that asks us either to accept this regime or else to renounce all hope for innovation. An additional possibility was exemplified in the recent past, when IPRs 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 emerging global IPR regime cannot succeed by showing merely that this regime is preferable to the complete absence of IPRs anywhere. Second, the social-utility argument for the ongoing IPR 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 patents and by expanding the innovation flow of new seeds and pharmaceuticals). On any cosmopolitan understanding of social utility, which gives equal weight to the well-being of rich and poor human beings alike, the new global IPR regime is greatly inferior to its more differentiated predecessor.

Responsibility for the IPR regime

But 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."[22] Even 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.

Second, most poor countries lacked the bargaining power needed to resist the imposition. All the Western free-trade rhetoric

[22] "White Man's Shame". *The Economist*. 1999, September 25, p. 89.

notwithstanding, the poor countries are required to pay for access to the huge markets of the rich. Any poor country is required to open its own markets widely to the corporations and banks of the rich countries and required also to commit itself to the costly enforcement of their IPRs. The World Intellectual Property Organization (WIPO), a specialized agency of the United Nations, has the task of "helping" poor countries enforce IPRs. The cost of such enforcement efforts cut 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."[23] And the extraction of monopoly rents for foreign corporations also raises prices in the poor countries, including prices charged for seeds and essential medicines. Poor countries deemed insufficiently aggressive in the enforcement of foreign IPRs are singled out in the "301 reports" of the US Trade Representative, held up for reprimand and exposed to actual or possible trade sanctions (www.ustr.gov).[24]

The third point we need to bear in mind is that the poor countries are heavily stratified. Even if an international treaty is disastrous for a country's poor, signing up to this treaty as proposed by the rich 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 comparable brutality and corruptness. 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.

[23] *Ibid.*

[24] This kind of relentless pressure goes a long way toward explaining why poor countries have rarely issued compulsory licences for patented medicines, even though they are legally entitled to do so pursuant to para. 6 of the 2001 Doha Declaration.

Volenti non fit iniuria

These reflections on the third point also speak to another popular defence of the new rules of the world economy. This defence 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 defence 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, it is still doubtful whether his consent can waive supposedly inalienable human rights of his subjects whom the rich countries' IPR initiative is depriving of secure access to essential medicines – including the human rights of children under five, who constitute about half of those killed by such deprivation.

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 military officers in the poor countries.

Yet the effects of this accepted international practice on the world's poor are devastating: the practice enables even the most hated, brutal, oppressive, corrupt, undemocratic, and unconstitutional 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 neighbouring 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 defence against the charge that the newly globalized IPR regime is harming the global poor, the present practice of international recognition is a further example of such harming.

What if we really cared about social utility?

We have seen that, on any plausible conception of social utility, the rich countries' IPR 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 very 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's chosen price, typically vastly higher than the marginal cost of production.[25]

Imagine for a moment that we really cared about social utility understood in the cosmopolitan way that gives equal weight to the well-being of rich and poor alike. If we did, 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 very cheaply or (by donation) cost-free. The

[25] Second-line AIDS and TB medicines are prominent examples.

other problem arises from the fact that poor populations face many serious health problems that are very rare among the affluent and therefore predictably ignored under a regime that forces pharmaceutical inventor firms to recoup their research and development costs from paying patients. These special 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 spent on controlling 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.

To make progress, we must understand the political obstacles. An intellectual property reform plan must not merely be *feasible*, such that, once implemented, it generates its own support from governments, pharmaceutical companies, and the general public (taking these three key constituencies as they would be under the reformed regime). A reform plan must also be *realistic*: it 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 fails these tests is destined to remain an idealistic dream. 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.

A cosmopolitan proposal: The Health Impact Fund

With generous funding from the Australian Research Council, the BUPA Foundation, and the European Union, an international team of researchers has been developing just such a politically realistic reform plan: proposing the creation of the Health Impact Fund (HIF), designed to stimulate pharmaceutical innovation while also reducing allocative inefficiencies.

Financed primarily by governments, this pay-for-performance scheme would give pharmaceutical innovators the option to register any new product. They would guarantee to make it available, wherever it is needed, at the lowest feasible cost of production and distribution. In exchange, each registered product would, during its first ten years on the market, participate in the HIF's annual reward pools, receiving a

share equal to its share of the assessed global health impact of all HIF-registered products.[26] The HIF would not require substantial additional taxation since government savings from lower-priced products would offset the cost of funding the reward pools.

The HIF achieves three key advances. It directs some pharmaceutical innovation toward the most serious diseases, including those concentrated among the poor. It makes all HIF-registered medicines cheaply available to all. And it incentivizes innovators to promote the optimal use of their HIF-registered medicines. Magnifying one another's effects, these advances would engender large health gains.

Because registration is optional, the HIF would be fully consistent with the TRIPS Agreement. Offering an additional arena where companies can compete, it would attract high-impact medicines some of which would not have been developed otherwise. Even for medicines that would have come on the market anyway, the HIF multiplies their global health impact by making them immediately accessible to poor people and by engendering their more careful deployment (avoiding drug-specific resistance, for instance). If it were found to work well, the HIF could be scaled up to attract an increasing share of new medicines.

To provide stable incentives, the HIF would need guaranteed financing some fifteen years into the future to assure pharmaceutical innovators that, if they fund expensive clinical trials now, they can claim a full decade of health-impact rewards upon market approval. Such a solid guarantee is also in the interests of the funders who would not want the incentive power of their contributions to be diluted through skeptical discounting by potential innovators. The guarantee might take the form of a treaty under which each participating country commits to the HIF a fixed fraction of its future gross national income (GNI). Backed by such a treaty, the HIF would automatically adjust the contributions of the various partner countries to their variable economic fortunes, would avoid protracted struggles over contribution proportions, and would assure each country that any extra cost it agreed to bear through an increase in the contribution schedule would be matched by

[26] Ten years corresponds roughly to the profitable period of a patent: under TRIPS, WTO members must offer patents lasting at least twenty years from the patent filing date which is typically many years before the medicine receives market clearance after clinical trials. Because some patents may outlast the reward period, HIF registration requires the registrant to offer a royalty-free open license for generic versions of the product following the end of the reward period.

a corresponding increase in the contributions of all other partner countries. Any country providing 1/n of the HIF's core funding will understand that each additional dollar it agrees to contribute will raise HIF rewards by n dollars – or by even more thanks to economies of scale achievable in the HIF's administration and health impact assessments. (If contribution increases were left to ad hoc negotiations, by contrast, then each additional dollar a country agreed to contribute would add only this one dollar to the HIF budget.) Tying contributions to GNIs would also eliminate uncertainty related to exchange and inflation rates, as each country would pay in its own currency.

In view of the great cost ($200 to $1300 million) of bringing a new medicine to market, and to take advantage of economies of scale in health impact assessment, the annual reward pools should be at least $6 billion (which is about five per cent of current pharmaceutical R&D spending worldwide). If all countries were to join up, each would need to contribute about 0.01 per cent of its GNI. If countries representing only a third of the global product participated, each would need to contribute a still-modest 0.03 per cent of its GNI – mitigated by massive cost savings their governments, firms, and citizens would enjoy from low-cost HIF-registered medicines.

Because HIF-registered medicines would be cheaply available everywhere, there would be no cheating problems as commonly attend any differential pricing schemes aimed to make a medicine more affordable to poor patients or in poor countries. The HIF's global scope also brings huge efficiency gains by diluting the cost of innovation without diluting its benefits.[27] By including all diseases as well as all patients on equal terms, the HIF fulfills the cosmopolitan principle invoked above.

The HIF has five main advantages over conventional innovation prizes, including advance market commitments and advance purchase commitments. First, it is a structural reform, establishing an enduring source of high-impact pharmaceutical innovations. Second, it is not disease-specific and thus much less vulnerable to lobbying by firms and patient groups. Third, conventional prizes must define a precise finish line, specifying at least what disease the sought medicine must attack, how effective and convenient it must minimally be, and how bad its side effects may be. Such specificity is problematic because it presupposes the

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

very knowledge whose acquisition is yet to be encouraged. Since sponsors lack this knowledge ahead of time, their specifications are likely to be seriously suboptimal: they may be too demanding, with the result that firms give up the effort even though something close to the sought medicine is within their reach, or they may be insufficiently demanding, with the result that firms, to save time and expense, deliver a medicine that is just barely good enough to win even when they could have done much better at little extra cost.[28] The HIF avoids this problem of the finish line by flexibly rewarding any new registered medicine in proportion to its global health impact. Fourth, formulated to avoid failure and in ignorance of the true cost of innovation, specific prizes are often much too large and thus overpay for innovation. The HIF solves this problem by letting its health impact reward rate adjust itself through competition: a high reward rate would correct by attracting additional registrations (producing an increase in the number of registered medicines) and an unattractively low reward rate would correct by deterring new registrations (producing a decrease in the number of registered medicines). Fifth, the HIF gives each registrant powerful incentives to promote the optimal end-use of its product: to seek its wide and effective use by any patients who can benefit from it.

The requisite global health impact assessment of HIF-registered products could be conducted in terms of quality-adjusted life years (QALYs), a metric that has been deployed for about two decades by academic researchers, insurers, NGOs, and government agencies. The assessment would rely on clinical and pragmatic trials of the product, on tracing (facilitated by serial numbers) of random samples of the product to end-users, and on statistical analysis of correlations between sales data (including time and place of sale) and target disease burden.

The HIF could use three methods (or a combination of these) to ensure the lowest feasible prices of registered products.[29] It could prescribe a maximum price determined by engineering estimates of the cost of production, which might be adjusted over time to reflect advances in manufacturing technology. Or, alternatively, the HIF could require open licensing of registered products, thus relying on competition

[28] For an excellent discussion, see Aidan Hollis, "Incentive Mechanisms for Innovation," *IAPR Technical Paper*, 2007, available at: www.iapr.ca/iapr/files/iapr/iapr-tp-07005_0.pdf, pp. 15–16.

[29] See Aidan Hollis, "The Health Impact Fund and Price Determination," *IGH Discussion Paper* no. 1 (2009), available at: www.yale.edu/macmillan/igh/files/papers/DP1_Hollis.pdf.

among generic producers to achieve a low price. Or, finally, the HIF could require each registrant to invite competitive tender bids from generic manufacturers and then to contract with the lowest bidder(s) to produce the global supply. These tender competitions, in which the registrant could also compete, might be repeated in two-year intervals, say, to take advantage of advances in manufacturing technology. The registrant would then distribute the product at the contract price plus reasonable distribution costs as determined by the HIF. These three methods might be combined in various ways, for example by allowing the registrant to choose from among two or three of them. In designing this part of the HIF scheme, the goal of low prices is paramount. A secondary objective is to simplify the global health impact assessments, which might become considerably more complex under the second method which, if it works well, would engender a large number of competing bioequivalent products.

There is no space here to discuss the design of the HIF in greater detail,[30] but what has been said should suffice to convey the basic idea. The HIF would give pharmaceutical innovators, for each of their new products, a standing option to forgo their patent-based pricing powers worldwide in exchange for a guaranteed payment stream based on this product's global health impact. Without revision of the existing patent regime, the HIF would thereby provide systemic relief for its seven drawbacks described above.

High prices would not exist for HIF-registered medicines. Innovators would typically not even want a higher price as this would reduce their health impact rewards by impeding access to their product by most of the world's population. The HIF counts health benefits to the poorest of patients equally with health benefits to the richest.

Diseases concentrated among the poor, insofar as they contribute substantially to the global burden of disease, would no longer be neglected. In fact, the more destructive ones among them would come to afford some of the most lucrative R&D opportunities for biotechnology and pharmaceutical companies. This would happen without undermining the profit opportunities such companies now enjoy by developing remedies for the ailments of the affluent.

Bias toward maintenance drugs would be absent from HIF-encouraged R&D. The HIF assesses each registered medicine's health impact in terms of how its use reduces mortality and morbidity worldwide – without

[30] See note 12, Hollis and Pogge and www.healthimpactfund.org.

regard to whether it achieves this reduction through cure, symptom relief, or prevention. This would guide firms to deliberate about potential research projects in a way that is also optimal for global public health – namely in terms of the expected global health impact of the new medicine relative to the cost of developing it. The profitability of research projects would be aligned with their cost effectiveness in terms of global public health.

Wastefulness would be dramatically lower for HIF-registered products. There would be no deadweight losses from large mark-ups. There would be little costly litigation as generic competitors would lack incentives to compete and innovators would have no incentive to suppress generic products (because they enhance the innovator's health impact reward). Innovators might therefore often not even bother to obtain, police, and defend patents in many national jurisdictions. To register a medicine with the HIF, innovators need show only once that they have an effective and innovative product.

Counterfeiting of HIF-registered products would be unattractive. With the genuine item widely available near or even below the marginal cost of production, there is little to be gained from producing and selling fakes.

Excessive marketing would also be much reduced for HIF-registered medicines. Because each innovator is rewarded for the health impact of its addition to the medical arsenal, incentives to develop me-too drugs to compete with an existing HIF-registered medicine would be weak. And innovators would have incentives to urge a HIF-registered drug upon doctors and patients only insofar as such marketing results in measurable therapeutic benefits for which the innovator would then be rewarded.

The last-mile problem would be mitigated because each HIF-registered innovator would have strong incentives to ensure that patients are fully instructed and properly provisioned so that they make optimal use (dosage, compliance, etc.) of its medicines, which will then, through wide and effective deployment, have their optimal public-health impact. Rather than ignore poor countries as unprofitable markets, pharmaceutical companies would, moreover, have incentives to work with one another and with national health ministries, international agencies, and NGOs toward improving the health systems of these countries in order to enhance the impact of their HIF-registered medicines there.

In all these ways, the HIF would align the interests of innovators with those of patients – interests that the current regime brings into

sharp opposition. The HIF also harmonizes the moral and prudential interests of innovators who must now all too often choose between recouping their R&D investments and preventing avoidable suffering and deaths.

In its early years, the HIF would make the greatest difference to diseases that are widespread and concentrated among the poor. Yet the HIF's reach would increasingly extend to diseases that are widespread among poor and affluent populations alike. Even if profit per patient is substantially smaller with HIF rewards than with traditional patent-protected mark-ups, the choice of HIF registration would often enable pharmaceutical innovators to earn a larger overall profit by helping a much larger patient population. In cases of uncertainty about which option is more lucrative, pharmaceutical innovators would be inclined to choose the HIF because they want to be, and to be seen as, contributors to global health when this is economically feasible.

Citizens of the richer countries would thus increasingly benefit from the HIF through lower drug prices, insurance premiums, or national health-care outlays. They would also benefit from HIF-stimulated research into neglected poor-country diseases, which would enable more effective responses to public health emergencies by increasing medical knowledge faster and by providing a stronger and more diversified arsenal of medical interventions. In addition, better human health around the world would reduce the threat from invasive diseases. As the SARS and swine flu outbreaks illustrate, dangerous diseases can rapidly spread to affluent countries which – given the current neglect of the medical needs of poor populations – are ill-prepared to cope with such challenges. By joining the HIF, an affluent country would also build goodwill in the poor countries by demonstrating in a tangible way concern for their horrendous public-health problems.

To be sure, for many citizens of affluent countries such prudential reasons pale beside the moral imperative to end the needless pain and dying among the world's poor. Creation of the Health Impact Fund would go a long way toward easing the disparities in access to medicines, which have been aggravated by the TRIPS Agreement.