The Health Impact Fund: better pharmaceutical innovations at much lower prices

THOMAS POGGE*

1. Introduction

The poverty endured by the bottom half of humankind poses serious dangers to their health and survival. The poor worldwide face greater environmental hazards than the rest of us: from contaminated water, filth, pollution, worms and insects. They are exposed to greater dangers from people around them: through traffic, crime, communicable disease and the cruelties of the more affluent. They lack means to protect themselves and their families against such hazards through clean water, nutritious food, good hygiene, ample rest, adequate clothing and safe shelter. They lack the means to enforce their legal rights or to press for political reform. They are often obliged by dire need or debt to incur additional health risks: by selling a kidney, for instance, or by accepting hazardous work in prostitution, mining, construction, domestic service, textile and carpet production. They lack financial reserves and access to public sources of medical knowledge and treatments, and therefore face worse odds of recovering from disease.

Mutually reinforcing, these factors ensure that the poor bear a hugely disproportionate burden of disease – especially of communicable, maternal, perinatal and nutritional conditions – and a hugely disproportionate share of premature deaths: 30 per cent of all deaths each year, 18 million, are from poverty-related causes. These much greater burdens of morbidity and premature mortality in turn entail large economic burdens that keep most of the poor trapped in lifelong poverty.

* This essay is part of a collective effort, funded by the Australian Research Council, the BUPA Foundation, and the European Commission to which Christian Barry, Laura Biron, Leila Chirayath, Kieran Donaghue, Jocelyn Finlay, Aidan Hollis, Miltos Ladikas, Matt Peterson, Michael Ravvin, Doris Schroeder, Michael Selgelid, Jie Tian, Ling Tong, Kit Wellman and Judith Whitworth have contributed substantially.

It is possible to make substantial progress against the global burden of disease ('GBD') directly. Existing huge mortality and morbidity rates can be dramatically lowered by reforming the way the development of new medical treatments is funded. I will sketch a concrete, feasible and politically realistic reform plan that would give medical innovators stable and reliable financial incentives to address the diseases of the poor. If adopted, this plan would not add much to the overall cost of global healthcare spending. In fact, on any plausible accounting, which would take note of the huge economic losses caused by the present GBD, the reform would actually pay for itself. Moreover, it would distribute the cost of global healthcare 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.

2. The problem

With medicines, the fixed cost of developing a new product is extremely high for two reasons. It is very expensive to research and refine a new medicine and then to take it through elaborate clinical trials and national approval processes. Moreover, most promising research ideas fail somewhere along the way and thus never lead to a marketable product. Both reasons combine to raise the research and development ('R&D') cost per new marketable medicine to somewhere around half a billion dollars or more. Commencing manufacture of a new medicine once it has been invented and approved is cheap by comparison. Because of this fixed-cost imbalance, pharmaceutical innovation is not sustainable in a free market system: competition among manufacturers would quickly drive down the price of a new medicine to near its long-term marginal cost of production, and the innovator would get nowhere near to recovering its R&D investment.

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

In the case of patents, many are willing to overlook the standard objections to monopolies – that these are economically inefficient or are immoral restrictions of freedom – because they 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 11 per cent per annum,¹ a ten-year effective patent life generates 68 per cent, and a fifteen-year effective patent life 82 per cent, of the profit (discounted to present value) that a permanent patent would generate.² 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 barred from producing, selling and buying a patented medicine without permission from the patentee. This restraint hurts generic producers and it also hurts consumers by depriving them of the chance to buy such medicines at competitive market prices. But consumers also benefit from the impressive arsenal of useful medicines whose development is motivated by the prospect of patent-protected mark-ups.

It may seem obvious that this benefit outweighs the loss of freedom. But we must consider that not everyone is either affluent enough to buy advanced medicines at very high prices or fortunate enough to need them only after patent expiration. Many human beings are trapped in severe poverty. Most of them derive no benefit from patented medicines because they cannot get access to them. These people can object that the patent regime gives them nothing in return for the freedom it deprives them of. If the freedom to produce, sell and buy advanced medicines were not curtailed, then the affluent would need to find another (for them possibly less convenient) way of incentivizing pharmaceutical research. But advanced medicines would then be

¹ Joseph A. DiMasi, Ronald W. Hansen and Henry G. Grabowski, 'The Price of Innovation: New Estimates of Drug Development Costs' (2003) 22 *Journal of Health Economics* 151.

² 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.

available at competitive market prices, and the poor would have a much better chance of gaining access to them through their own funds or with the help of national or international government agencies or non-governmental organizations. The loss of freedom patents inflict on the global poor – and they number in the billions – is a huge loss in terms of disease and premature death. There is no associated gain that could compensate those suffering these losses; and the gains that patents bring to the affluent cannot possibly justify these losses either.

This objection was less pertinent until the 1990s, when strict patent rules were mostly confined to the affluent states, which allowed the less-developed countries to have weaker patent protections or none at all. This exemption of poor countries had little effect on innovation incentives because, in these countries, those able to afford advanced medicines at patent-protected prices are few, relative to the one billion population of the high-income countries. But the exemption brought relief to many poor residents of poor countries: to all those who obtained at a competitive market price some new medicine they would not have been able to obtain if it had been under patent in their country.

The diversity of national regulations was destroyed in the 1990s when a powerful alliance of industries (software, entertainment, pharma and agribusiness) induced the Clinton Administration and other wealthy states to press strong, globally uniform intellectual property rules upon the world. Acceptance of this regime, enshrined in the Trade-Related Aspects of Intellectual Property Rights Agreement of 1994 ('TRIPS Agreement' or 'TRIPS'),³ was made a condition of World Trade Organization ('WTO') membership, which, it was then promised, would allow poor countries to reap large benefits from trade liberalization. While the affluent states have been slow to lower their trade barriers and subsidies, they have worked hard towards instituting strong intellectual property rights in the less-developed countries – with devastating effects, for instance, on the evolution of the HIV/AIDS epidemic.

The world responds to the catastrophic health crisis among the global poor in a variety of ways: with the usual declarations, working papers, conferences, summits and working groups first and foremost, of course; but also with efforts to fund delivery of medicines to the poor through intergovernmental initiatives, governmental programmes,

³ Marrakesh Agreement Establishing the World Trade Organization, opened for signature 15 April 1994, 1867 UNTS 3, annex 1C (Agreement on Trade-Related Aspects of Intellectual Property Rights) (entered into force 1 January 1995) ('TRIPS Agreement').

public-private partnerships, and through medicine donations from pharmaceutical companies; and with various efforts to foster the development of new medicines for the diseases of the poor, and various prizes as well as advance purchase commitments and advance market commitments.⁴

Such a busy diversity of initiatives looks good and creates the impression that a lot is being done to solve the problem. And most of these efforts are really doing good by improving the situation relative to what it would be otherwise. Still, these efforts are not nearly sufficient to protect the poor. It is unrealistic to hope that enough billions of dollars will be devoted to neutralizing the cost imposed on the world's poor by the globalization of twenty-year patents. And it is even more unrealistic to hope that such billions will reliably and efficiently be spent year after year. It makes sense then to look for a more systemic solution that addresses the global health crisis at its root. Involving institutional reform, such a systemic solution is politically more difficult to achieve. But, once achieved, it is also politically much easier to sustain. And it pre-emptly most of the huge and collectively inefficient mobilizations currently required to sustain the many stop-gap measures, which can at best only mitigate the effects of structural problems they leave untouched.

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

- **High prices.** While a medicine is under patent, it will be sold near the profit-maximizing monopoly price, which is largely determined by the market demand 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 1,000 per cent are not exceptional.⁵ 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

⁴ Details of these initiatives (and their drawbacks) are discussed in Aidan Hollis and Thomas Pogge, *The Health Impact Fund: Making New Medicines Accessible for All* (2008) ch. 9, www.yale.edu/macmillan/igh/hif_book.pdf at 16 February 2009.

⁵ In Thailand, Sanofi-Aventis sold its cardiovascular disease medicine Plavix for 70 baht (\$2.20) per pill, sixty times more than the price at which the Indian generic firm Emcure agreed to deliver the same medicine (clopidogrel). See Oxfam International, 'Investing for Life: Meeting Poor People's Needs for Access to Medicines through Responsible Business Practices' (Briefing Paper No 109, Oxfam, November 2007) 20.

among the poor – no matter how widespread and severe – are not attractive targets for pharmaceutical R&D. This is so because the demand for such a medicine drops off very steeply as the patentee enlarges the mark-up. There is no prospect, then, of achieving high sales volume *and* a large mark-up. Moreover, there is the further risk that a successful research effort will be greeted with loud demands to make the medicine available at marginal cost or even for free, which would force the innovator to write off its R&D 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 has become known as the 10/90 problem, alluding to only 10 per cent of all pharmaceutical research being focused on diseases that account for 90 per cent of the GBD.⁶

- **Bias towards maintenance drugs.** Medicines can be sorted into three categories: curative medicines remove the disease from the patient's body; maintenance drugs improve wellbeing and functioning without removing the disease; and 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.⁷ 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 countries for possible infringements of their patents. Huge amounts are spent in many jurisdictions on costly litigation that pits generic companies, with strong incentives to

⁶ See Global Forum for Health Research, *The 10/90 Report on Health Research 2003–2004* (2004), www.globalforumhealth.org at 16 February 2009.

⁷ See Michael Selgelid, 'Ethics and Drug Resistance' (2007) 21 *Bioethics* 218.

challenge any patent on a profitable medicine, against patentees, whose earnings depend on their ability to defend, extend and prolong their patent-protected mark-ups. Even greater costs are due to the dead-weight loss 'on the order of US\$200 bn' worldwide 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.⁸

- **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 do not really need for diseases they do not really have (and sometimes for invented pseudo-diseases).⁹
- **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

⁸ Personal communication (13 November 2007) from Aidan Hollis, based on his rough calculation. For some discussion of alternative calculations see Aidan Hollis, 'An Efficient Reward System for Pharmaceutical Innovation' (Working Paper, University of Calgary, 2005) 8, where he quantifies the dead-weight 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.'

⁹ See the special issue on disease mongering in the *Public Library of Science Medicine* (2006) 3, 425, collections.plos.org/plosmedicine/diseasemongering-2006.php at February 2009.

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 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.

Contemplating these seven problems together, we see another reason to aim for a comprehensive and permanent solution in preference to the stop-gap measures that have been implemented and proposed: the practical value of efforts to mitigate one of the seven problems may be greatly reduced by one of the other problems that remains unaddressed; and efforts to mitigate one problem may aggravate another. For example, a drug donation for the benefit of the poor, intended to mitigate the problem of high prices, may actually do more harm than good because of the weak health infrastructure (last-mile problem) in the recipient countries. Lacking competent medical instruction and package inserts in their own language, poor patients may fail to take the medicine in the right doses, at the right times, or for the appropriate length of time. Such patients may not merely remain sick; they may also develop and spread drug-resistant strains of the disease, which (as in the case of multi-drug-resistant and extensively drug-resistant tuberculosis) can pose grave dangers to people everywhere.

Counter-productive effects can arise also from compulsory licences that some governments have issued or threatened to issue in order to gain for their populations cheaper access to patented medicines. Though specifically permitted by the TRIPS Agreement as reaffirmed in the Doha Declaration,¹⁰ compulsory licences are energetically resented by pharmaceutical companies, and governments daring to issue such licences are routinely censured and penalized by these companies and by the rich-country governments doing their bidding. By issuing a

¹⁰ See Ministerial Declaration on the TRIPS Agreement and Public Health: Adopted on 14 November 2001, WTO Doc WT/MIN(01)/DEC/1 (2001) [4]–[6]; TRIPS Agreement, above n. 3, articles 8(1), 27(2).

compulsory licence, a government authorizes the production and marketing of a cheaper generic version of a patented medicine on condition that the authorized generic firm pays a small licence fee to the patentee. Such a licence, and even the mere threat of one, will typically cause the price of the relevant medicine to fall substantially in the relevant country. But this welcome relief from the problem of high prices also aggravates the neglect of diseases concentrated among the poor. Pharmaceutical companies spend less on the quest for vital medicines – especially ones with a substantial share of their potential market in less-developed countries – when the uncertainties of development, testing and regulatory approval are compounded by the additional unpredictability of whether and to what extent successful innovators will be allowed to recoup their R&D investments through undisturbed use of their market exclusivity.

3. Reasoning

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

This question becomes even more pressing when we realize that including the poor adds nothing to the cost of innovation. It is a wonderful thing about the products of thought that their cost is independent of the number of beneficiaries. The intellectual labours of composing a novel are exactly the same, regardless of whether it has millions of readers or none at all. Likewise for discovering a new medically effective molecule. Millions can benefit from such intellectual efforts without adding at all to their cost. And this renders morally irresistible the conclusion that poor people, when their lives are at stake, must not be prevented from buying medicine from willing

suppliers at competitive market prices. A compulsory licence secures this freedom for the poor.

But what about the innovator who has put in the effort and expense to achieve the innovation? Does not the innovation belong to him or her or it – to give or withhold or sell at will? Appealing to a Lockean natural right of appropriation, such an innovator might liken himself to someone who, by ‘mixing his labour’ with a formerly un-owned object while leaving ‘enough and as good’ for others, acquires this object and then denies others the freedom to use it. But this analogy is crucially defective. By asserting intellectual property rights, the medical researcher is denying others not merely the freedom to use what he has legitimately acquired, but also the freedom to use what they themselves have legitimately acquired. Through his invention, the rest of us supposedly lose our freedom to do what he did: to transform materials we legitimately own into a substance of the kind he first produced. Far from supporting monopoly rights in pharmaceuticals, the philosophical tradition friendliest to property rights thus refutes such intellectual property rights.¹¹

The defender of intellectual property rights might reply that it is destructive of innovation to permit generic producers to copy an invention without having to buy the inventor’s licence. Such permission would deprive us all of the powerful new medicines pharmaceutical innovators keep on producing.

This argument constitutes a change of venue, defending now patents not in the courtroom of natural rights but in the courtroom of mutual advantage. Does this defence succeed? It is indisputable that powerful new medicines whose development was motivated by the hope for profits have greatly benefited some patients: namely those affluent enough to buy them at monopoly prices or fortunate enough to need them after patent expiration. If all human beings were so affluent or fortunate, then patents might be defensible as in everyone’s best interest: it would then be rational for all of us to accept the cost of laying down our rights to produce, sell and buy a new medicine invented by another in exchange for the much greater benefit of having available a broad and powerful arsenal of pharmaceuticals.

In fact, however, many human beings are trapped in severe poverty. Most of them derive little or no benefit from the marvellous arsenal of available medicines because they cannot, at prevailing prices, get access

¹¹ For a more extensive rejection of the Lockean claim (with specific discussion of Robert Nozick), see Hollis and Pogge, *The Health Impact Fund*, above n. 4, 62–8.

to them. For these people – and they number in the billions – it would be highly irrational to agree to lay down their freedom so that the affluent can more successfully use patents to stimulate pharmaceutical innovation. In the real world, the poor do not give such highly irrational consent. The often devastating cost is imposed on them by others who, for their own advantage, interpose the barrier of patents between poor people and the generic companies willing to supply the medicines they urgently need. This interposition is a grievous injustice that kills millions of poor people each year.

This injustice is manifest in national legislation: in India, for instance, where the poor have recently lost their legal freedom of access to medicines at competitive market prices. It is also manifest in international trading rules such as the TRIPS Agreement, which required India to implement these legislative changes as a condition of the limited access WTO membership affords Indian exporters to the markets of affluent countries. Perhaps the governments of India and other less-developed countries made a reasonable choice when they imposed unjust pharmaceutical access rules upon their poor for the sake of gaining a little more fairness in international trade. But the powerful affluent countries devising and imposing the present WTO regime have no such excuse. They are acting unjustly by pressing weaker countries to inflict this injustice on their poor. If rich countries and their citizens desire medical innovation, then they must find ways of funding it that either leave the freedom of the poor unreduced or else adequately compensate the poor for the loss of freedom imposed upon them.

Because it would be difficult, if not impossible, adequately to compensate poor people for disease and death, let us consider ways of funding pharmaceutical innovation that would not deprive the poor of their freedom of access to existing medicines at competitive market prices. The problem here is that, if the poor are left this freedom, it is difficult to collect from anyone the monopoly rents that stimulate pharmaceutical innovation. Though the affluent are often willing to buy advanced medicines at prices far above the marginal cost of production, many of them prefer to buy cheaper, even illegally. And clever brokers and smugglers, too, stand ready to exploit any substantial differential between the price charged to the rich and the competitive market price charged to the poor. Split markets with large price differentials thus generate unfairness as smugglers and the selfish affluent benefit at the expense of innovators and the honest affluent. More to the point, allowing the poor their freedom of access at competitive market prices

substantially reduces the monopoly rents that can be extracted from affluent patients and thereby also the incentives of pharmaceutical companies to make large R&D investments in the first place.

To avoid all these problems with large price differentials, it is best then to level pharmaceutical prices in the opposite direction: instead of unjustly imposing monopoly prices also on the poor (which effectively excludes most of them from advanced medicines), we should grant open access at competitive market prices also to the affluent. In this way, we avoid the problem of high prices in an efficient way. We also eliminate high mark-ups entirely and thereby avoid the problems associated therewith: smuggling, wastefulness, counterfeiting, excessive marketing and the bias towards maintenance drugs.

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

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

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

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

Most prominent among pull programmes are prize competitions that promise a reward to the innovator who is first able to produce a medicine that meets certain specifications. This reward can be specified as some monetary amount or as an Advance Purchase Commitment ('APC') or Advance Market Commitment ('AMC'). Such rewards have been described with considerable ingenuity.¹² They clearly can be a valuable complement to existing patent rewards and have the potential of stimulating the development of medicines for currently neglected diseases.

Nonetheless, such ad hoc prize competitions have four drawbacks. First, politicians, bureaucrats or experts play a crucial role by deciding which diseases should be researched, how the sought remedy should be specified and how large a reward should be promised for a remedy meeting these specifications, inviting incompetence, corruption, gaming and lobbying by companies and patient groups. But the planners' own incentives to stimulate 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 utility of their efforts.

Second, ad hoc rewards involve excessive specificity. Each reward must define a precise finish line, specifying at least what disease the medicine must attack, how bad the side effects of the medicine may be, and how effective and convenient it must minimally be. Such specificity is problematic because it presupposes the very knowledge whose acquisition is yet to be encouraged. Thus the sponsors' specification is likely to be seriously suboptimal even if they are single-mindedly devoted to the

¹² See especially Michael Kremer and Rachel Glennerster, *Strong Medicine: Creating Incentives for Pharmaceutical Research on Neglected Diseases* (2004).

goal of improving public health. Such suboptimality can take two forms. The specification may be overly demanding in at least one dimension, with the result that innovators give up the effort even though something close to the sought solution is within their reach. And the specification may be insufficiently demanding in some dimension(s), with the result that innovators, to save time and expense, deliver products that are just barely good enough to win the prize even when they could have done much better at little extra cost.¹³

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

A fourth serious defect of ad hoc rewards is that they fail to address the last-mile problem, which is especially severe in the context of currently neglected diseases that mostly affect the poor. The fact that a new vital medicine is available in large quantities, or can be produced very cheaply by generic producers, does not yet give poor populations real access to it. The reward pulls innovators to the invention of a new safe and effective medicine or even to its production in large quantities. But it does not pull this medicine the rest of the way to the patients who need it.

4. Solution

The exclusion of the poor by the existing patent regime requires reform. Given the foregoing discussion, a straightforward and moderate reform would create a supplementary mechanism that, by addressing the needs of the poor, would remedy the injustice now imposed upon them. This reform proposal comprises six elements. First, just as the patent regime provides a *general* innovation incentive, so its complement encourages pharmaceutical innovation through an incentive that is specified in

¹³ For an excellent discussion, see Aidan Hollis, 'Incentive Mechanisms for Innovation' (Technical Paper No TP-07005, Institute for Advance Policy Research, University of Calgary, June 2007)15–16.

general terms: as a promise to reward *any* successful new medicine in proportion to its success. This kind of mechanism has been described as a *comprehensive* AMC.¹⁴ Second, while the patent regime rewards medicines on the basis of the market demand each generates and then satisfies, thereby effectively excluding the poor, its complement gives equal standing to all by defining success simply in terms of human health. On this complementary track, the success of a medicine is assessed by the reduction in human morbidity and premature mortality it achieves – regardless of whether these harms are averted from rich or poor patients. Third, in order to help overcome the last-mile problem, the rewards available under the complementary mechanism should be tied not to what a medicine can do, but to what it *actually* achieves in the world. Fourth, when such a general mechanism provides large enough health impact rewards, it will attract sufficient innovation and sufficient efforts to ensure real access to new medicines worldwide. This avoids any need for compulsion. Innovators can be left free to choose between the two tracks, developing on the new track high-impact medicines needed also by many poor patients and on the conventional patent track low-impact medicines desired by the more affluent. Making the health-impact track optional is also crucial for the political success of the proposal. Fifth, in order to reinforce the incentive towards facilitating real access, health impact rewards should be conditional on the medicine being priced no higher than the lowest feasible cost of production and distribution.

Sixth, health impact rewards should be funded by governments as a public good. In order to minimize burdens and dead-weight losses due to taxes, the cost should be spread as widely as possible. This suggests that the complementary funding mechanism should be global (rather than national) in scope. The reasons that make the reform compelling in any one country or region make it compelling everywhere. Moreover, global scope avoids the problems associated with large price differentials. Global scope also brings huge efficiency gains by diluting the cost of the scheme without diluting its benefits: no matter how many beneficiaries we may add, the cost of achieving an innovation remains the same even while its aggregate benefit increases with the number of beneficiaries.¹⁵ Finally, an international

¹⁴ Aidan Hollis, 'The Health Impact Fund: A Useful Supplement to the Patent System?' (2008) 1 *Public Health Ethics* 124.

¹⁵ 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

agreement would also reinforce the commitment of individual countries to the scheme. Pharmaceutical innovation is therefore best encouraged by promising to reward any safe and effective new medicine in proportion to its *global* health impact. Such a promise constitutes an AMC that is *fully* comprehensive: by including not merely all diseases but also all patients.

The proposal is then for the creation of a new international agency that offers to reward any new medicine based on its health impact during its first decade or so.¹⁶ This Health Impact Fund ('HIF') would provide ample rewards for the development of new high-impact medicines without excluding the poor from their use.

To provide stable incentives, member states must guarantee funding some fifteen years into the future to assure pharmaceutical innovators that, if they invest in expensive clinical trials now, they can claim a full decade of health-impact rewards upon marketing approval.¹⁷ 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 sceptical discounting by potential innovators. States might guarantee fixed annual pools to be shared among registered medicines in proportion to their respective health impacts (subject to a reward rate ceiling) or they might promise a fixed monetary amount per unit of health impact.¹⁸ These two design options differ in how they allocate the inevitable burden from uncertainty about how much health impact HIF-registered products will achieve in aggregate. The former solution makes the cost of the HIF predictable and is therefore more attractive to governments; but it imposes one more risk upon potential innovators by leaving them in the dark about the rate of reward per unit of health impact. The latter option removes this uncertainty from innovators, but then imposes on

reduce the probability that this disease will adapt and rebound with a drug-resistant strain: see Selgelid, 'Ethics and Drug Resistance', above n. 7.

¹⁶ This corresponds roughly to the effective patent life of twenty-year pharmaceutical patents, which are typically filed many years before marketing approval.

¹⁷ To allow for the registration of newly trialled traditional medicines and of new indications of existing medicines, the HIF should not require a patent as a precondition of registration. This issue is discussed by Katharine Liddell in this volume as well as by Talha Syed, 'Should a Prize System for Pharmaceuticals Require Patent Protection for Eligibility?', Discussion Paper Number 2, www.healthimpactfund.org.

¹⁸ Which for this discussion I assume is measured in quality-adjusted life years ('QALYs'). The QALY is a common measure of gains against the mortality and morbidity that constitute the GBD. It can be refined in various ways which I lack the space to discuss here. Basically, one QALY is an additional year of healthy life or a longer additional period of impaired life (e.g., 1.25 additional years with a 20 per cent impairment of age-specific functioning).

governments considerable uncertainty about what the HIF will cost each year.¹⁹ There are also intermediate design options that split the burden of uncertainty between governments and pharmaceutical innovators.²⁰

So constructed, the HIF is scalable, allowing governments to scale it up if it proves successful (downscaling is constrained by the fifteen-year guarantee). Any such scaling-up can be financed through an increased commitment by the member states and/or through the accession of new members.

The establishment and scaling-up of the HIF would be facilitated by a rule that divides the cost of the HIF in proportion to the member states' respective gross national incomes ('GNIs'). Thus, if one member state's GNI is 3.7 times that of another, then the contribution assigned to the former will be 3.7 times that assigned to the latter. Such rigidity has three main advantages. First, the contributions of the various partner countries are automatically adjusted in a way that tracks their varying fortunes – fast-growing countries automatically assume a larger share while countries in recession (declining GNI) find their burden alleviated. Second, it pre-empts protracted struggles over contribution proportions such as have marred the United Nations. Third, rigidity assures each country that any extra cost it agrees to bear by supporting an increase in the contribution schedule, say, is matched precisely by a corresponding increase in the contributions of all other member states.

If all countries of the world were to agree to join the effort, each would contribute less than 0.01 per cent of its gross national income for the first US\$6 billion. As citizens, we would all pay an additional 0.01 per cent of our gross income in taxes (US\$1 for every \$10,000 in gross income). If countries representing only one third of global national incomes were willing to participate, their citizens would contribute 0.03 per cent of their gross incomes: still a trivial amount relative to its impact and mitigated, of course, by the much greater affordability of HIF-registered medicines.

Let us recapitulate how the HIF would provide a full systemic solution to the seven problems described earlier:

- **High prices** would not exist for HIF-registered medicines. Innovators would typically not even want a higher price as this would reduce their

¹⁹ This may not be unacceptable. If more taxpayer money is spent because the HIF stimulates more successful innovation than expected, then health gains and consequent economic benefits for taxpayers will also be greater than expected.

²⁰ For further discussion of such design options, see Hollis and Pogge, *The Health Impact Fund*, above n. 4, ch. 2.

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 substantially aggravate the GBD, would no longer be neglected. In fact, the more destructive ones among them would come to present some of the most lucrative R&D opportunities for biotechnology and pharmaceutical companies. This would happen without undermining the profit opportunities such companies now enjoy by developing remedies for the ailments of the affluent.
- **Bias towards 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 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 dead-weight 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. (Getting a patient switched from a competitor's product to one's own equally good product is very profitable under the present system. But if the latter product is HIF-registered, then the switch is not

profitable because it brings no health improvement.) And innovators would have incentives to urge an 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 towards improving the health systems of these countries in order to enhance the impact of their HIF-registered medicines there.

5. Conclusion

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

A partial answer is that the efforts encouraged by HIF rewards would not be neatly confined to new medicines. Once a firm has registered a new drug, its reward will depend on how this drug affects the evolution of mortality and morbidity attributable to its target disease (the disease for which it is indicated). This impact will depend on many factors, some of which – for example, the quality of healthcare delivery in poor countries – the firm can affect. By helping to improve such healthcare delivery, an innovator can magnify its medicine's impact, which is strongly affected by the extent to which doctors and nurses are locally available, know about the medicine, have it on hand, prescribe it, ensure that patients have access to it in the best dosage and in sufficient quantity, and instruct patients in its proper use.

This answer does not fully overcome the objection. There are diseases – simple diarrhoea, for instance – against which new medicines would be of limited help, if any. Why should not efforts to reduce such diseases by securing access to off-patent medicines, to clean drinking water or to sanitation be funded insofar as they are no less cost-effective than the Health Impact Fund? I have no objection to such an extension of the reward scheme here sketched. We can think of this scheme as the central module of a larger health reform project. Once this central module is specified and implemented, it can certainly be extended to other social factors essential to human health. It makes sense, nonetheless, to begin with the central module that will provide a useful paradigm for possible extensions and an impetus for further reform.

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

I am aware that I have not had the space to discuss fully how the proposed HIF should best be designed. This is evidently a highly complex question. We have an interdisciplinary and international team – supported by the Australian Research Council, the BUPA Foundation and the European Commission – hard at work detailing workable solutions to the remaining challenges. Our work is documented, with some time lag, at www.HealthImpactFund.org. A book, describing the proposal in more detail, is available there.

The Health Impact Fund: a critique

KATHLEEN LIDDELL*

1. Introduction

Despite the remarkable ability of medical science to treat, cure and prevent human suffering, the reality is that relatively few people benefit from this knowledge. The principal reason is poverty, or more accurately the unequal distribution of wealth. While the rich have more than enough to afford complex new treatments for cancer, heart disease, diabetes and infertility (amongst many other disorders), the poor struggle to afford even the most basic healthcare services. And while the diseases of the rich present lucrative new markets for medical research, the diseases of the poor are largely invisible to profit-oriented scientists, so few drugs are available. These two problems have been dubbed the crises of access and innovation.¹

The patent system, although significant for the economic sustainability of medical science, has exacerbated these problems. The strongest justification for the patent system is utilitarian. The argument is that in return for investing in the risky business of developing an invention and disclosing it to the public, the inventor is given up to twenty years of exclusivity during which they have the sole power within the jurisdiction of the patent to exploit the invention, or to license others to do so.² This is the foundation

* With special thanks to Laura Biron for her helpful and insightful comments on an earlier draft of this chapter. This chapter's discussion of the HIF idea is based mainly on Aidan Hollis and Thomas Pogge, *The Health Impact Fund: Making New Medicines Accessible for All* (2008), www.yale.edu/macmillan/igh/hif_book.pdf and therefore does not reflect later refinements that were stimulated in part by the critical attention the proposal received at and subsequent to the Australian National University's workshop on *Incentives for Global Public Health: Patent Law and Access to Essential Medicines* (Canberra, 26–28 May 2008).

¹ Maxwell Morgan, 'Medicines for the Developing World: Promoting Access and Innovation in the Post-TRIPS Environment' (2006) 64 *University of Toronto Law Review* 45, 48.

² This is the typical utilitarian justification offered for patent protection. Other theories exist. A familiar one is the argument that a patent is the natural right of an inventor who has invested intellectual labour, but amongst other problems, this struggles to explain why subsequent independent inventors who labour using entirely their own resources to

Connecting
International Law
with
Public Law

This portrait of the global debate over patent law and access to essential medicines focuses on public health concerns about HIV/AIDS, malaria, tuberculosis, the SARS virus, influenza and diseases of poverty. The essays explore the diplomatic negotiations and disputes in key international forums, such as the World Trade Organization, the World Health Organization and the World Intellectual Property Organization.

Drawing upon international trade law, innovation policy, intellectual property law, health law, human rights and philosophy, the authors seek to canvass policy solutions that encourage and reward worthwhile pharmaceutical innovation while ensuring affordable access to advanced medicines. A number of creative policy options are critically assessed, including the development of a Health Impact Fund, prizes for medical innovation, the use of patent pools, Open Source drug development and forms of 'creative capitalism'.

Thomas Pogge is Leitner Professor of Philosophy and International Affairs at Yale University, Professorial Fellow at the ANU Centre for Applied Philosophy and Public Ethics (CAPPE), Research Director at the Oslo University Centre for the Study of Mind in Nature (CSMN), and Adjunct Professor at the University of Central Lancashire.

Matthew Rimmer is a Senior Lecturer and Associate Director of research at the ANU College of Law, Australian National University, and an Associate Director of the Australian Centre for Intellectual Property in Agriculture.

Kim Rubenstein is Professor and Director of the Centre for International and Public Law (CIPL) in the ANU College of Law, Australian National University.

Pogge
Rimmer
Rubenstein

Incentives for Global
Public Health

Connecting
International Law
with
Public Law

Incentives for Global Public Health

Patent Law and Access to
Essential Medicines

Edited by

Thomas Pogge
Matthew Rimmer
Kim Rubenstein

2448374

A.N.U. LIBRARY

LAW LIB
KC241.1
.I53
2010

CAMBRIDGE
UNIVERSITY PRESS
www.cambridge.org

ISBN 978-0-521-11656-5

9 780521 116565

cipl
centre for international and public law

CAMBRIDGE

INCENTIVES FOR GLOBAL PUBLIC HEALTH

This portrait of the global debate over patent law and access to essential medicines focuses on public health concerns about HIV/AIDS, malaria, tuberculosis, the SARS virus, influenza and diseases of poverty. The essays explore the diplomatic negotiations and disputes in key international forums, such as the World Trade Organization, the World Health Organization and the World Intellectual Property Organization.

Drawing upon international trade law, innovation policy, intellectual property law, health law, human rights and philosophy, the authors seek to canvass policy solutions that encourage and reward worthwhile pharmaceutical innovation while ensuring affordable access to advanced medicines. A number of creative policy options are critically assessed, including the development of a Health Impact Fund, prizes for medical innovation, the use of patent pools, Open Source drug development and forms of 'creative capitalism'.

THOMAS POGGE is Leitner Professor of Philosophy and International Affairs at Yale University, Professorial Fellow at the ANU Centre for Applied Philosophy and Public Ethics (CAPPE), Research Director at the Oslo University Centre for the Study of Mind in Nature (CSMN) and Adjunct Professor at the University of Central Lancashire.

MATTHEW RIMMER is a senior lecturer and Associate Director of Research at the ANU College of Law, and Associate Director of the Australian Centre for Intellectual Property in Agriculture.

KIM RUBENSTEIN is Professor and Director of the Centre for International and Public Law (CIPL) at the ANU College of Law, Australian National University.

CONNECTING INTERNATIONAL LAW WITH PUBLIC LAW

This series of books flows from workshops bringing public and international lawyers and public and international policy makers together for interdisciplinary discussion on selected topics and themes. It aims to broaden both public and international laws' understanding of how these two areas intersect. Until now, international and public law have mainly overlapped in discussions on how international law is implemented domestically. This series is unique in consciously bringing together public and international lawyers to consider and engage in each other's scholarship.

Series Editors

Professor Kim Rubenstein, Australian National University
Professor Thomas Pogge, Yale University

Books in the series

Incentives for Global Public Health: Patent Law and Access to Essential Medicines

Edited by Thomas Pogge, Matthew Rimmer and Kim Rubenstein

Sanctions, Accountability and Governance in a Globalised World

Edited by Jeremy Farrall and Kim Rubenstein

INCENTIVES FOR GLOBAL PUBLIC HEALTH

Patent Law and Access to Essential Medicines

Edited by

THOMAS POGGE,

MATTHEW RIMMER

and

KIM RUBENSTEIN

CAMBRIDGE
UNIVERSITY PRESS

CAMBRIDGE UNIVERSITY PRESS
Cambridge, New York, Melbourne, Madrid, Cape Town, Singapore,
São Paulo, Delhi, Dubai, Tokyo

Cambridge University Press
The Edinburgh Building, Cambridge CB2 8RU, UK

Published in the United States of America by Cambridge University Press, New York

www.cambridge.org
Information on this title: www.cambridge.org/9780521116565

© Cambridge University Press 2010

This publication is in copyright. Subject to statutory exception
and to the provisions of relevant collective licensing agreements,
no reproduction of any part may take place without the written
permission of Cambridge University Press.

First published 2010

Printed in the United Kingdom at the University Press, Cambridge

A catalogue record for this publication is available from the British Library

Library of Congress Cataloguing in Publication data
Incentives for global public health : patent law and access to essential medicines / edited by
Thomas Pogge, Matthew Rimmer, and Kim Rubenstein.
p. cm. – (Connecting international law with public law)
Includes bibliographical references.
ISBN 978-0-521-11656-5 (hardback)

1. Pharmaceutical policy. 2. Patent laws and legislation 3. Drugs – Patents. 4. Patents
(International law) I. Pogge, Thomas Winfried Menko. II. Rimmer,
Matthew. III. Rubenstein, Kim. IV. Title. V. Series:
Connecting international law with public law.

[DNLM: 1. Legislation, Drug – organization & administration. 2. Drugs, Essential – supply
& distribution. 3. Health Services Accessibility – legislation & jurisprudence. 4. Human
Rights. 5. International Cooperation. 6. Patents as Topic – legislation & jurisprudence.

QV 33.1 I36 2010
RA401.A1143 2010
362.17'82–dc22
2010010211

ISBN 978-0-521-11656-5 Hardback

Cambridge University Press has no responsibility for the persistence or
accuracy of URLs for external or third-party Internet websites referred to in
this publication, and does not guarantee that any content on such websites is,
or will remain, accurate or appropriate.

CONTENTS

<i>Contributors</i>	viii
<i>Series Editors' Preface</i>	xvii
<i>Editors' Preface</i>	xix

Introduction: Access to essential medicines: public health and international law	1
THOMAS POGGE, MATTHEW RIMMER AND KIM RUBENSTEIN	

PART I International trade 33

1. TRIPS and essential medicines: must one size fit all? Making the WTO responsive to the global health crisis	35
ROCHELLE C. DREYFUSS	
2. The TRIPS Waiver as a recognition of public health concerns in the WTO	56
ANDREW D. MITCHELL AND TANIA VOON	
3. Public law challenges to the regulation of pharmaceutical patents in the US bilateral free trade agreements	77
HITOSHI NASU	
4. Global health and development: patents and public interest	101
ELIZABETH SIEW-KUAN NG	

PART II **Innovation** 133

5. The Health Impact Fund: better pharmaceutical innovations at much lower prices 135
THOMAS POGGE
6. The Health Impact Fund: a critique 155
KATHLEEN LIDDELL
7. A prize system as a partial solution to the health crisis in the developing world 181
WILLIAM W. FISHER AND TALHA SYED
8. Innovation and insufficient evidence: the case for a WTO-WHO Agreement on Health Technology Safety and Cost-Effectiveness Evaluation 209
THOMAS FAUNCE

PART III **Intellectual property** 233

9. Opening the dam: patent pools, innovation and access to essential medicines 235
DIANNE NICOL AND JANE NIELSEN
10. Open Source drug discovery: a revolutionary paradigm or a Utopian model? 263
KRISHNA RAVI SRINIVAS
11. Accessing and benefit sharing avian influenza viruses through the World Health Organization: a CBD and TRIPS compromise thanks to Indonesia's sovereignty claim? 284
CHARLES LAWSON AND BARBARA ANN HOCKING
12. The Lazarus Effect: the (RED) Campaign and creative capitalism 313
MATTHEW RIMMER

PART IV **Healthcare** 341

13. Beyond TRIPS: the role of non-state actors and access to essential medicines 343
NOAH BENJAMIN NOVOGRODSKY

14. Securing health through rights 357
KATHARINE G. YOUNG
15. The role of national laws in reconciling constitutional right to health with TRIPS obligations: an examination of the *Glivec* patent case in India 381
RAJSHREE CHANDRA
16. Tipping point: Thai compulsory licences redefine essential medicines debate 406
JONATHAN BURTON-MACLEOD

Bibliography 425

Index 486

CONTRIBUTORS

Editors

Having received his PhD in philosophy from Harvard University, PROFESSOR THOMAS POGGE is Leitner Professor of Philosophy and International Affairs at Yale University, Professorial Fellow at the ANU Centre for Applied Philosophy and Public Ethics (CAPPE), Research Director at the Oslo University Centre for the Study of Mind in Nature (CSMN) and Adjunct Professor at the University of Central Lancashire. He is Editor for Social and Political Philosophy for the *Stanford Encyclopedia of Philosophy* and a member of the Norwegian Academy of Science. With support from the Australian Research Council, the BUPA Foundation and the European Commission, he currently heads a team effort towards developing a complement to the pharmaceutical patent regime that would improve access to advanced medicines for the poor worldwide. His recent publications include *World Poverty and Human Rights*, 2nd edn. 2008; *Global Justice* and *Global Ethics*, both 2008; and *John Rawls: His Life and Theory of Justice* and *Freedom from Poverty as a Human Right*, both 2007.

DR MATTHEW RIMMER is a senior lecturer and Associate Director of Research at the ANU College of Law, and Associate Director of the Australian Centre for Intellectual Property in Agriculture. He holds a BA (Hons) and a University Medal in literature, and an LLB (Hons) from the Australian National University. Dr Rimmer received a PhD in law from the University of New South Wales for his dissertation on *The Pirate Bazaar: The Social Life of Copyright Law*. He is a member of the ANU Climate Change Institute and a director of the Australian Digital Alliance. Dr Rimmer is the author of *Digital Copyright and the Consumer Revolution: Hands off my iPod* (2007) and *Intellectual Property and Biotechnology: Biological Inventions* (2008). He edited the

collection *Patent Law and Biological Inventions* (2006). Dr Rimmer was a chief investigator in an ARC Discovery Project, 'Gene Patents in Australia: Options for Reform' (2003–5), and an ARC Linkage Grant, 'The Protection of Botanical Inventions' (2003). He has published widely on copyright law and information technology, patent law and biotechnology, access to medicines, clean technologies and traditional knowledge.

PROFESSOR KIM RUBENSTEIN is Professor and Director of the Centre for International and Public Law (CIPL) at the ANU College of Law, Australian National University. A graduate of the University of Melbourne and Harvard University, Professor Rubenstein's current research projects are at the cutting edge of the intersection between public and international law. Her public law work spans constitutional and administrative law, and also includes her expertise in citizenship law. Her international law work focuses on the status of nationality. Her book, *Australian Citizenship Law in Context* (2002) represents the foundation of her continued scholarly work, looking at the disjuncture between the exclusive legal notion and the more inclusive normative understanding of citizenship.

Other Contributors

JONATHAN BURTON-MACLEOD holds a BSc from Harvard University, a law degree from Queen's University, Canada, and a Masters in Law from Harvard Law School. Burton-MacLeod's initial focus was biochemistry and he worked at the Centers for Disease Control, Atlanta. In law school, his focus remained on international health, with study conducted at the University of Cape Town Faculty of Law. His graduate law degree focused on theories of law and society in the globalization of law, viewed through the lens of public health. Since finishing, much of Burton-MacLeod's research has focused on American and comparative Constitutional law. He was a lecturer at the ANU College of Law. Burton-MacLeod is currently an Assistant Professor and Assistant Dean (Research) at Jindal Global Law School and Assistant Director at the Centre for Global Governance and Policy.

RAJSHREE CHANDRA is a Senior Lecturer at Janki Devi Memorial College, Delhi University with fifteen years' teaching experience in the

Department of Political Science. She has completed a Masters and MPhil from the Centre for Political Studies, Jawaharlal Nehru University (JNU) (New Delhi), and her Doctorate is from the Centre for the Study of Law and Governance (JNU). Her doctoral dissertation is an inquiry into the moral premises of intellectual property rights, as encompassed by the TRIPS regime. Her research interests concern the impact of patent rights on healthcare.

PROFESSOR ROCHELLE C. DREYFUSS is the Pauline Newman Professor of Law at New York University School of Law. She holds BA (Wellesley College) and MS (University of California) degrees in Chemistry and a law degree (Columbia Law School), and she clerked for Chief Judge Wilfred Feinberg of the US Court of Appeals for the Second Circuit and Chief Justice Warren E. Burger of the US Supreme Court. She is a member of the National Academy of Sciences (NAS) Committee on Science, Technology and the Law and the National Institute of Health's Advisory Committee on Genetics, Health and Society, as well as the American Law Institute, where she was Co-reporter for its Project on Intellectual Property: Principles Governing Jurisdiction, Choice of Law, and Judgments in Transnational Disputes. She is a past consultant to the Federal Courts Study Committee, the Presidential Commission on Catastrophic Nuclear Accidents and the Federal Trade Commission. She was also a member of NAS Committees on Intellectual Property in Genomic and Protein Research and Innovation and Intellectual Property Rights in the Knowledge-Based Economy.

ASSOCIATE PROFESSOR THOMAS FAUNCE (BA/LLB (Hons), BMed, PhD) has a joint position in the ANU College of Law and Medical School at ANU. He has directed two three-year ARC research projects on (1) the impact of international trade agreements on Australian medicines policy and (2) regulation of nanomedicine in Australia. He has been a consultant for UNESCO on its global ethics and health law database and published widely in this field. His latest book is *Who Owns our Health? Medical Professionalism, Law and Leadership beyond the Age of the Market State* (2007).

PROFESSOR WILLIAM FISHER received his undergraduate degree (in American Studies) from Amherst College and his graduate degrees (JD and PhD in the History of American Civilization) from Harvard

University. Between 1982 and 1984, he served as a law clerk to Judge Harry T. Edwards of the US Court of Appeals for the DC Circuit and then to Justice Thurgood Marshall of the US Supreme Court. Since 1984, he has taught at Harvard Law School, where he is currently the Hale and Dorr Professor of Intellectual Property Law and the Director of the Berkman Center for Internet and Society. His academic honours include a Danforth postbaccalaureate fellowship (1978–82) and a postdoctoral fellowship at the Center for Advanced Study in the Behavioral Sciences in Stanford, California (1992–3).

ASSOCIATE PROFESSOR BARBARA ANN HOCKING is an academic at QUT Faculty of Law. She has been a visitor at the Faculty of Law at the University of Tasmania for two years. She is the editor of *Towards a Nexus of Law and Biology: New Ethical Challenges* (2009) and was recently awarded an Australian Linkage International Fellowship (ARCIF) to work on intersections between avian influenza planning and human rights. She is currently preparing a second edition of her book *Liability for Negligent Words* (1999) with Scott Guy.

DR CHARLES LAWSON is a senior research fellow with ACIPA and an associate professor at the Griffith Law School at Griffith University. Dr Lawson's research interests include some aspects of intellectual property, competition, trade, access, taxation, public and administrative law and risk assessment and management.

DR KATHLEEN LIDDELL (DPhil (Oxon), LLB (Hons), BSc (Melb), MBioethics (Monash)) is the Herchel Smith Lecturer in Intellectual Property Law at Cambridge University and a fellow of Downing College. Her research focuses on the legal and ethical frameworks surrounding medical research, biotechnology and bioinformation. Her research benefits from funding provided by the Wellcome Trust, the Cambridge Genetics Knowledge Park and the Sasakawa Peace Foundation. It forms part of a programme of investigations organized by the Centre for Intellectual Property and Information Law and the Cambridge Centre for Medical Genetics and Policy.

DR ANDREW MITCHELL is an Associate Professor at Melbourne Law School. He has studied law at the University of Melbourne, Harvard Law School and Cambridge University. In addition to his Melbourne teaching, Dr Mitchell has taught WTO law to undergraduate and

postgraduate students at Bond University, Monash University and the University of Western Ontario, and to Australian and overseas government officials at the Australian Department of Foreign Affairs and Trade and the International Development Law Organization respectively. His monograph *Legal Principles in WTO Disputes* was published in 2008.

DR HITOSHINASU joined the ANU College of Law in December 2006. Prior to his appointment to the ANU, he was a part-time lecturer at the University of Sydney, teaching international law. He completed a PhD in 2006 by submitting a doctoral thesis entitled *Precautionary Approach to International Security Law: A Study of Article 40 of the UN Charter*.

ASSOCIATE PROFESSOR ELIZABETH SIEW-KUAN NG has been teaching intellectual property law at the Faculty of Law, National University of Singapore since 1986. She is the author of several books and has published widely and delivered papers at numerous international conferences on intellectual property law. She was a consultant to the World Intellectual Property Organization ('WIPO'), Switzerland; a visiting scholar to the US Court of Appeal for the Federal Circuit, Washington DC; and tutor in IP law of the WIPO Worldwide Academy, Switzerland. She served on many national and international projects to advise on intellectual property laws. Professor Ng regularly gives opinions on intellectual property law to clients in the public and private sectors. She holds an LLB (Hons) from the University of London and an LLM (First Class) from the University of Cambridge. She was awarded the Sweet & Maxwell Law Prize (1981) and the Faculty of Law prize (1983) from the University of London and the Clough prize (1984) from the University of Cambridge. She is also a barrister-at-law of the Middle Temple, England, an advocate and solicitor of the Supreme Court of Singapore, a fellow of the Cambridge Commonwealth Society, University of Cambridge and Team Leader (Information Communication Technology section) of the East Asian International Economic Law and Policy ICT Research Network of the University of Hong Kong.

PROFESSOR DIANNE NICOL is a professor in the Law Faculty at the University of Tasmania and a deputy director of the Centre for Law and Genetics (CLG), a cross-institutional research group based at the

University of Tasmania and Melbourne University. She teaches in the areas of intellectual property law, equity, media law, IT law and biotechnology and the law. She is Associate Dean for Research in the Law Faculty and Graduate Research Co-ordinator. She is also Chair of the University Animal Ethics Committee. Her research focuses on intellectual property issues in health and biotechnology, particularly on use of patented inventions.

DR JANE NIELSEN is a lecturer in law at the Law Faculty, University of Tasmania. Dr Nielsen's primary research interests concern the intersection of intellectual property and competition law, particularly as these issues pertain to the medical biotechnology industry. Dr Nielsen completed her PhD thesis in this area and has published a number of related papers. She also has an interest in the issue of compulsory licensing and its role in ensuring access to technologies. Her current project is to consider the role of patent pooling in facilitating access to, and distribution of, key biotechnology research tools and technologies.

PROFESSOR NOAH NOVOGRODSKY is an associate professor at the University of Wyoming law school and the former head of the International Human Rights Program at the University of Toronto Faculty of Law. Professor Novogrodsky has been a visiting professor at Georgetown University Law Center and a Schell fellow at Yale Law School. Professor Novogrodsky holds a BA degree from Swarthmore College (Political Science and English Literature), an MPhil Degree in International Relations from Cambridge University and a Juris Doctor from Yale Law School. Professor Novogrodsky's current research agenda focuses on the impact of AIDS treatment on the field of human rights law.

DR KRISHNA RAVI SRINIVAS is an associate fellow with RIS researching intellectual property rights and trade and environment issues. He holds a PhD from National Law School University, Bangalore. He has been a visiting scholar on a Fulbright Fellowship at the Law School, University of Pennsylvania, a visiting scholar at the Law School, Indiana University, Bloomington, a post-doc fellow at the South Centre, Geneva and a member of Visiting Faculty at IIM-Bangalore. His articles have been published in, *inter alia*,

Economic & Political Weekly, *EOLSS Encyclopaedia*, *Environmental Politics*, *International Social Science Journal* and *Asian Journal of WTO & International Health Law and Policy*. His research interests include use of Open Source models in biodiversity, drug discovery/development, biodiversity/biocommons and intellectual property rights.

TALHA SYED is an Assistant Professor at the University of California, Berkeley Law School, where he teaches and researches on intellectual property (with a focus on patents), torts, health law and legal theory. He has a BA (Hons) from the University of Western Ontario, an LLB (gold medallist) from the University of Victoria and is an SJD (doctoral) candidate at Harvard University. His academic honours include an Academic Fellowship from the Petrie-Flom Center for Health Law Policy, Biotechnology and Bioethics at Harvard Law School, research awards from the Weatherhead Center for Justice, Welfare and Economics at Harvard University and the Social Science and Humanities Research Council of Canada, and several Certificates for Distinction in Teaching from Harvard College.

DR TANIA VOON is an associate professor at Melbourne Law School and a former legal officer of the Appellate Body Secretariat of the World Trade Organization ('WTO'). She has previously practised law with Mallesons Stephen Jaques and the Australian Government Solicitor and taught law at Monash University, Bond University and the University of Western Ontario. She completed her PhD at the University of Cambridge and her LLM at Harvard Law School. Her book, *Cultural Products and the World Trade Organization*, was published in 2007.

KATHARINE YOUNG is a research fellow at the Regulatory Institutions Network at ANU. She earned her BA and LLB (Hons) from the University of Melbourne and an LLM at Harvard Law School. She was an SJD candidate at Harvard Law School where she held a graduate fellowship at the Edmond J. Safra Foundation Center for Ethics. She has served as Consultant Scholar at the NYU School of Law's Center for Human Rights and Global Justice, as Assistant to the Project Director of Health Rights and Ghana's Poor for Harvard Law School and the Fulbright Foundation, and as a graduate fellow at Harvard University's Project on Justice, Welfare and Economics. In 2001, she was Associate

to Justice Michael Kirby in the High Court of Australia. Her current fields of research include comparative constitutional law, law and development, law and economics, and international human rights. Her scholarly publications include 'The Minimum Core of Economic and Social Rights: A Concept in Search of Content' in the *Yale Journal of International Law* (2008).