

Drug access, patents and global health: ‘chaffed and waxed sufficient’

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ABSTRACT *In July 2000 the UN Committee on Economic, Social and Cultural Rights issued a General Comment on the Right to the Highest Attainable Standard of Health. At paragraph 10 the Committee makes the following admission: ‘Since the adoption of the International Covenant on Civil and Political Rights and the International Covenant on Economic, Social and Cultural Rights in 1966 the world health situation has changed dramatically and the notion of health has undergone substantial changes and widened in scope. More determinants are being taken into consideration, such as resource distribution and gender differences. A wider definition of health also takes into account such socially related concerns as violence and armed conflict. Moreover, formerly unknown diseases, such as HIV and AIDS, and others that have become more widespread, such as cancer, as well as the rapid growth of the world population, have created new obstacles for the realisation of the right to health which need to be taken into account when interpreting article 12.’¹ The need to understand why and how ‘the notion of health has undergone substantial changes and widened in scope’, the forces that are contributing to this redefinition, and the implications for governments, multinational pharmaceutical companies and ordinary people is the subject of this article. In particular global health is assessed according to the extent of global access to life improving-medicines, and the surmountable barriers that prevent this.*

On 24 September 2001 Tsapi Thathe, a young man living with HIV, was shot and killed in Soweto by people intent on stealing his cell-phone. Tsapi was a volunteer for the AIDS Counselling and Care Trust (ACCT). He was also an active member of the Treatment Action Campaign (TAC), involved in campaigns to reduce the price of patented essential medicines, thereby hoping to postpone his inevitable illness and premature death caused by HIV. In April 2001 he was briefly imprisoned for participating in an illegal demonstration at the head office of the Pharmaceutical Manufacturers’ Association (PMA) in Johannesburg. Tsapi’s death points to the tenuousness of ‘health’ in Africa and other parts of the ‘developing world’. The Human Immunodeficiency Virus (HIV) is the greatest modern threat to health, but there is a myriad of other variables, many as

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arbitrary as war and crime, that affect morbidity and mortality ('health'). For poor people these proximal factors often operate concurrently, creating an impact on physical and mental health whose aetiology, as Jonathan Mann started to hint, is still far from clear.²

Today the notion of global health is a misnomer. The divide between rich industrialised countries and the rest of the world has become great. In Afghanistan the probability of dying between the ages of 15 and 59 is 348 per thousand males; in Kenya 591; and in the USA it is 148.³ The burden of disease in the USA is one-fifth of that in Africa. This divide is easily bridged by means of modern transport—but less easily by medicine. Today it is possible to board a plane in Johannesburg—a city in a country where the prevalence of HIV infection among pregnant women was 24.8% in 2000 and where 22 million people 'survive' on less than R500 (US\$50) per month—and disembark 12 hours later in the USA or Europe, countries where HIV prevalence is well below 1% and where poverty is confined to relatively small groups of people.

The ill-health curtain is drawn across a growing social divide between the world's populations. Throughout much of the developing world many aspects of society are out of control. Even though there is a semblance of governance, if one scratches the surface of poor countries, one finds that many of the social goods that cohere Western societies are almost non-existent, and thus the compact between people, law and governments is often flimsy and fragile. In many countries of Africa and Eastern Europe, for example, there is limited access to justice, barely contained crime and the disintegration of society (and often governance) into fiefdoms that derive their power from access to resources.

In this respect, it is important at the outset of this article to place a note of caution concerning the terminology we use to describe the global community. If we use terminology like 'developing countries', we give the impression that the whole world is moving in the same direction, albeit at varying rates. The whole world is not moving in the same direction. Many so-called 'developing countries' are more accurately described as undeveloping countries. They are going backwards. Confirmation of this can be found in the *Human Development Reports* produced annually by the UNDP. On a whole range of vital indicators, development is now being reversed. In South Africa in 1992 two decades of progress in reducing infant mortality were put into reverse thrust.⁴ Infant mortality is on the rise again. Adult life expectancy is going down. Poverty is increasing.

AIDS is a contributor to this because HIV does two things. First, HIV takes advantage of entrenched fault lines in society, of the inequities and inequalities, in order to spread. Second, HIV makes these fault lines far, far wider. This is very apparent in 'post-apartheid' South Africa, where the people who have access to advanced medical care (including anti-retroviral medicines) are predominantly white and where the people who only have access to sub-standard care are black. Thus does HIV, and other causes of illness, widen the divisions that already exist. Inequality affects health and ill-health creates new inequality. Indeed, from multi-drug resistant TB in Russia's prisons,⁵ to AIDS in Zimbabwe's rural areas,⁶ crime and the collapse of health services, the despair and social disintegration that this is contributing to are all connected. Politics, economics, law, 'human rights' and

medicine all occupy places in a continuum that is either *for* health or *against* health. At the moment it is, arguably, against global health.

The right to health

Recognition of the interconnections between health and society are not new.⁷ In fact, it was explicitly recognised by the drafters of the Universal Declaration of Human Rights (UDHR), who situated the right to health in the context of the right of everyone to:

“a standard of living *adequate* for the health and well-being of himself and his family, including food, clothing, housing and medical care and necessary social services ...”⁸

Implicitly therefore the Universal Declaration recognises that declines in ‘standards of living’ will negatively influence health. The UDHR might, thus, be said to have been an attempt to establish as a principle the duty of global society to guarantee to all its populations a minimum standard of living as a threshold for the right to health. Clearly, this has not been successful. Since 1948, when the UDHR was adopted by the UN General Assembly, the right to health has surfaced repeatedly in a range of international instruments, most clearly in the International Covenant on Economic, Social and Cultural Rights (ICESCR) which promises the ‘right of everyone to the highest attainable standard of physical and mental health’.⁹ However, in qualifying the UDHR’s right to ‘a standard of living adequate to health’ and reformulating it as the right to the ‘highest attainable’ standard of health the ICESCR laid the foundation for a profound tension between what is the ‘highest attainable’ national and the ‘highest attainable’ international standard of health. This tension increases exponentially with the divergence in the wealth of nations.

It is this unresolved and deepening tension that is, arguably, now at the crux of global health or ill-health—because what is attainable on the basis of national resources is not the same as what is attainable on the basis of international resources. This is particularly poignant in a global society where many of the historical trappings of the nation-state are withering away, and where trans-national governments are emerging. This tension is thrown into relief, but not resolved, by the ICESCR’s non-justiciable Article 2, whereby:

Each State party ... undertakes to take steps, individually and through international assistance and co-operation, especially economic and technical, to the maximum of its available resources, with a view to achieving progressively the full realisation of the rights recognised in the present Covenant ...

and more recently in the General Comment’s unambiguous claim that:

The right to treatment includes the creation of a system of urgent medical care in cases of accidents, epidemics and similar health hazards, and the provision of disaster relief and humanitarian assistance in emergency situations. The control of diseases refers to States’ individual and joint efforts to, inter alia, make available relevant technologies.

The failure of the international covenants to influence state (and private) practice

in relation to duties to promote global health now stands apparent. In the context of the HIV pandemic the reticence of rich states to make technology and resources available to control and treat the greatest modern threat to global health has caused a growing global disease burden that experts now concur 'might destroy the Third World's arduous efforts to pull itself out of perpetual poverty and disease into political stability and economic growth'.¹⁰ The AIDS epidemic, and the epidemics of opportunistic infections, are altering the balance between public health and medicine. This needs to be explicitly recognised.

In the 1960s and 1970s much emphasis, correctly, was placed on the prevention of illness at the level of primary health care. This culminated in 1978, when the International Conference on Primary Health Care declared that primary health care was the key to achieving the goal of health for all by 2000. The importance of medicine *per se* to global public health was downplayed, even by people such as Jonathan Mann, who wrote that the 'contribution of medicine to health, while undeniably important (and vital in certain situations), is actually quite limited'.¹¹ This emphasis needs to be retained. But side by side with this the emergence of treatable pandemics (HIV/AIDS), the resilience of others (TB), breakthroughs in some crucial areas of medicine and paralysis in others, place unparalleled importance on access to drugs as part of the right to health. Health services are needed to deliver medicines to people who are already sick—as much as to prevent illness. Thus, those who seek to misrepresent advocates of treatment access, by claiming that the focus on medicines is one-sided, miss the point. In many countries the health infrastructure envisaged by Alma Ata exists—although more is needed. But the existence of health services without the ability to deliver medicines simply leads to the decay and demoralisation of these services. Absent a vital part of the formula and the whole equation collapses.

Thus it is that the capacity to pay the inflated price of patented medicines becomes fundamental to the contemporary global health equation, and has created a new vicious circle that perpetuates global ill-health inequalities. Because of their high price, the purchasers of medicines are primarily people in the first world. The diseases they buy drugs for are primarily non-communicable lifestyle diseases, recreating the incentive for further research into medicine for these illnesses, at the expense—largely—of further urgent research into the communicable diseases of the third world.¹² Countries with a high GDP are able to spend disproportionate amounts on health. According to Benatar, for example, the USA spends 50% of annual global expenditure on health care on 5% of the world's population. By contrast, countries with meagre resources are engaged in a constant balancing act, weighing social needs such as access to health care services against other genuine and sometimes non-genuine priorities. There is no purpose in denying that developing countries frequently misuse even the limited resources they have, often in an attempt to ape their counterparts in the West. But this should not detract from identifying the underlying and self-perpetuating causes of ill-health. In South Africa, for example, R40 billion (\$4 billion) is being spent on re-armament, by a government that simultaneously argues that it lacks the resources to expand access to voluntary HIV counselling and testing services.¹³ The incongruity of this led a recent newspaper columnist to note that 'buying equipment for which there was no need (South Africa has no military threat to its

security) was bad economics: "Imagine if someone suggested spending tens of billions on 100 state of the art hospitals, with almost no other use, in the very unlikely event that a specific disease might hit SA. They would be scoffed at."¹⁴

The juxtapositions within 'global health' are also shocking. In Monteval, Canada researchers are about to embark on a heroin trial that will involve expenditure of \$20 000–\$25 000 per person, per year.¹⁵ These amounts are jarring to people in the third world who are told that an annual course of anti-retrovirals, at roughly \$750 per person per year, is not cost-effective (it would be much lower if generic companies could manufacture their products, but we will come to this argument). The only conclusion that can be drawn is that some kinds of life are not considered worthy of health before calculations of cost-effectiveness are made. This creates a hollow ring to the assertion in the Universal Declaration of Human Rights that 'all human beings are born equal in dignity and rights'. More appropriate to modern conditions might be Snowball's revision (in *Animal Farm*): 'All pigs are equal, but some pigs are more equal than others'.

In the light of all this evidence, it is arguable that the notion of health as a human right has been under covert, and sometimes overt, attack for several decades, particularly by the economists of economic liberalisation and 'free trade' at the World Bank. Early signs of the attack on health as a human right were evident during the tenures of Margaret Thatcher as British Prime Minister and Ronald Regan as US President. Ironically, however, it was only after their political demise, under more liberal industrialised country governments, that the most refined institutional attacks on health took place. The most infamous of these was linked to the establishment of the World Trade Organization (WTO) and its expansion of Western intellectual property law (suddenly as a 'right') into the sphere of pharmaceutical research and development, as codified in the Agreement on Trade Related Intellectual Property Rights (TRIPS).

The consequence of the erosion of the principle that health is a fundamental human right will, if not forestalled, be disastrous. However, the difficulty facing advocates for health is that global ill-health cannot be remedied in isolation from other social ills. It is insufficient to say that an overriding objective should be once again(?) to entrench the right of 'everyone' to health in national and international law in a manner that compels expenditure of necessary resources on health nationally and internationally. This conclusion is easily drawn from the *symptoms*. Identifying, unravelling and acquiring consensus on the *causes* of global ill-health is more complex, especially since some are virological, some political and some legal.

The politics of AIDS

The HIV/AIDS epidemic is in its twentieth year. The fact that it is now leading to a rapid deterioration of global health and global health services is being documented by numerous authors.¹⁶ It is also closely monitored by UNAIDS and the World Health Organisation (WHO) who put out bi-annual reports on the global AIDS epidemic. In this respect the late Renée Sabatier's warning of the 'danger of half of us turning into AIDS voyeurs, standing around watching others die' seems prophetic.¹⁷

Today there is an intense international focus on HIV/AIDS. UN Secretary-General Kofi Annan has described AIDS an international emergency and in June 2001 the United Nations General Assembly convened its first Special Session on HIV/AIDS (UNGASS). A global health fund has been launched—albeit with paltry sums contributed by industrialised countries.

There is no good that can be said about an epidemic that kills three million people per annum and is placing massive strain on health services (if so they may be called) except that the HIV/AIDS epidemic may at least have brought with it the benefit of visibly drawing attention to the underlying deterioration in global health and of the structures and institutions that are needed to support health.

In the discussion that AIDS activists have forced into the public domain about how to treat the symptoms of HIV infection, as well as the causes of disproportionate vulnerability of people in developing countries to HIV, we are challenged to confront and identify much of the aetiology of global ill-health and to debate whether the paucity of the global response to preventing and treating AIDS is because of a 'manufactured scarcity' of knowledge and medicines or for other reasons.¹⁸ We are forced to analyse 'the pathologies of power' and consider, as Farmer argues, whether we have indeed 'sacrificed equity for efficacy' on the basis of unsubstantiated claims of limited resources.¹⁹

But first, in the context of global ill-health, it is necessary to devote a few words to 'globalisation'—particularly as it has been blamed for many modern ills. Globalisation is inescapable. There is little benefit to fulminating against it, because, as Marx and Engels explained in relation to capitalism, it is an objectively inevitable—not a subjectively created—state of social organisation reflecting the degree of development of what they termed the forces of production. Thanks to a revolution in communications technology, capitalism outgrew national markets. Technology, trade, invention and—in this context—medicine cannot be rebottled in the nation state. To return to an ethic of human rights does not mean that we must de-globalise the world. That will not ever happen. However, it is necessary to draw attention to the way in which the speed of globalisation of certain tangible world-goods (commerce, trade and communications) has frequently outstripped the globalisation of the intangibles (morality, identity and ethics) that regulate human society as much as law. In fact, despite forces such as CNN and MTV that globalise identity, the ethnic conflicts that have accompanied the economic upheavals caused by the penetration of the capitalist market into former no-go areas has led to isolationist national and religious movements that have further fragmented human society—often with disastrous consequences for health. In this respect globalisation has proved to have as much potential to divide the world as it does to unite it.

Analysing global health epitomises the fact that certain aspects of globalisation have far outstripped others. As Garrett and a host of other authors have illustrated, the economic and political processes that unfolded in the postwar, post-colonial period made many people in the world more vulnerable to diseases than they were before. They also facilitated the speed at which bacteria and viruses can travel. Consequently certain types of disease have been globalised. The greatest tragedy, however, is that, while there has been a globalisation of medical research, and a globalisation of knowledge about medicine, there has

been only a partial globalisation in the availability of medicines. A doctor working in impoverished areas of Botswana or Malaysia can read about effective medicines on the internet, but has no hope of obtaining these medicines for her patients or getting to a health centre that can obtain them. This is a disparity of enormous proportions.

A concrete example will help illustrate this point. In July 2000 the pharmaceutical company Glaxo Wellcome received approval from the European Union's Committee for Proprietary Medicinal Products (CPMP) for Trizivir, a triple combination anti-retroviral pill. In a press release Glaxo described the benefits of the medicine as 'its potent HIV activity in antiretroviral naïve patients and that only one tablet twice daily is required, with no food or water restrictions. Furthermore, the simplified regimen of Trizivir may help to improve adherence to treatment, one of the key challenges in managing the treatment of HIV infection.'²⁰ Given its simplicity Trizivir would currently be an ideal medicine for people with AIDS in developing countries where multi-drug regimens often cause problems with adherence and tolerance of medicines. However, its cost (\$2409 per patient per annum) and its patent status means that it is unlikely that people in the developing world are going to see much Trizivir for quite some time, even though it is an indicated medicine for people with AIDS.²¹

On the other hand, the Indian pharmaceutical company Cipla has developed a similar triple-combination pill, Triomune, that ought to be similarly well tolerated. Cipla has offered publicly to make it available at a price of \$350 per patient per year.²² But in most countries, including South Africa, it would be unlawful to import, manufacture or distribute Triomune in view of the patents that are held on its parts. If doctors put Triomune in people's mouths, they are breaking the law. In South Africa if Cipla even tries to submit Triomune for registration with the Medicines Control Council (MCC), it is breaking patent law.

Why do we have this problem? Is it because Jean-Paul Garnier, the CEO of GlaxoSmithKline, is a wicked man? No, the problem is with the commodification and privatisation of medicine and with the evolution of something that for many people is as essential for human life as water into something that makes profits for shareholders in countries of the first world. And this is made possible by the silent, but very deliberate, shifting of certain 'rights' away from the values that inspired them. Patent or 'intellectual property' rights are the case in point.

Drugs and the politics of patents

Historically, the granting of a patent was a reward, bestowed by the state, to an inventor *in return* for making the invention available to the public. The *quid pro quo* of the 'right' to profit from a period of market exclusivity and deny other people this license, was (a) that the product would be made available and (b) that the state, even if generally bound by the patent, should retain the right to 'use an invention for public purposes on such conditions as may be agreed upon with the patentee' (this is the language used in section 4 of South Africa's *Patents Act*, no 57 of 1998). Where agreement could not be reached the state could override the patent by means of what is now commonly called a 'compulsory licence'.²³

In the four centuries of its application patent law has had its fair share of

controversy and criticism—but perhaps none as fierce as that which now rages around the patenting of new medicines, particularly those used in the treatment of AIDS. The target of much of this criticism is the WTO's agreement on TRIPS.²⁴ TRIPS is criticised because of the manner in which, from the mid-1990s, it has made the extension of the US standard of patent law to pharmaceutical products and processes a condition for membership of the WTO. Understanding how this happened and where patent law has been perverted, if indeed it has, is assisted by recapturing some of its history.

In 1850 Charles Dickens penned an article entitled 'A Poor Man's Tale of a Patent'. In it the imaginary author, 'Old John', lamented the difficulty encountered by poor people in obtaining a patent for an invention. Old John saw a patent as a right, as a means to protect and exploit his invention—a protection against other innovators, with more resources, prone to stealing, exploiting and profiting from poor people's intellectual property. John complains, 'Is it reasonable to make a man feel as if, in inventing an ingenious improvement meant to do good, he has done something wrong?' This reference to Dickens points to the manner in which, even in the 19th century, the ability to obtain a patent had become an art, vulnerable to abuse and horizontal collaboration between a powerful state and powerful monopolies. At the end of the piece Old John complains that 'the whole gang of Hanapers and Chaffwaxes [administrative bureaucrats responsible for the onerous filing of patents] must be done away with ... England has been chaffed and waxed sufficient.'²⁵

More than a century later, the problem remains. In his description of the political negotiations that led to the ratification of TRIPS Michael P Ryan talks of 'advocacy made persuasive by the market and the political power of the industry sector making the demand on the political system'.

In democracies, business enterprises 'are taller and richer than the rest of us and have rights that we do not have. Their political impact differs from and dwarfs that of the ordinary citizen.'²⁶

TRIPS is one of the fruits of the Uruguay Round of trade negotiations that were 'successfully' concluded in 1995 with the establishment of the World Trade Organization and the Dispute Settlement Understanding. TRIPS is binding on all WTO members. Although developing countries 'wanted no part of reforms to intellectual property laws' a range of pressures was brought to bear to bring about their submission and a further shift of power was effected to industrialised countries.²⁷

The inclusion of discussion on intellectual property in the Uruguay round was primarily at the instigation of two US companies, Pfizer and IBM. According to Ryan, these companies—and the other US industry leaders they drew around them—'demonstrated in the 1980s and 1990s an impressive capacity to push their interests in Washington and Geneva', so much so that, while in 1986 US trade negotiators did not 'know much about patents', by 1990 'the institutionalization of intellectual property rights had become one of the highest trade related priorities of the US government'. Why was this? According to Ryan the pharmaceutical companies justified their lobbying on the basis of the 'potential for future foreign investment and sales'. Put another way, Pfizer, in its far-sighted way,

understood—perhaps through an analysis of the burgeoning AIDS epidemic—that certain types of disease were rapidly being globalised. Alongside the communications revolution which spread information and knowledge about medicine more effectively than traditional advertising, this was likely to create a global demand for certain types of medicines. In the postwar pre-TRIPS period some developed and developing countries chose either not to permit patenting of essential goods such as medicine (Brazil and India) or to create laws where compulsory licensing of medicines was legitimised in the public interest (Canada). This permitted reverse engineering of medicines by generic companies like Cipla. This situation was challenged but tolerated (albeit grudgingly) until changing patterns in global health began to present a threat to the degree of profitability of patented medicines, not only in the domestic market where the generic manufacturer existed, but also in a far more sizeable amalgam of developing country markets. In a globalised world, particularly one that has glorified competition, the existence of interchangeable alternative medicines, costing a fraction of the price of the patented version, was seen as threat.²⁸

Thus it was by design and not by evolution or accident that intellectual property law was extended worldwide in the middle of the 1990s—and drew medicines into its embrace. The effect of TRIPS is to undermine the ability of countries such as India, Thailand and Brazil to continue to manufacture (‘appropriate’) and produce significantly cheaper generic versions of medicines that are still under patent in industrialised countries. It is also greatly, to extend and strengthen the monopoly power of a handful of giant pharmaceutical companies. Again the advent of anti-retroviral medicines (all under patent) that are needed to treat AIDS has brought the consequences of TRIPS for global health into an intense light that might otherwise have been postponed.

TRIPS has been much maligned, and certainly it is problematic that all the world’s countries, despite different stages of economic and social development, regardless of disease burden and health needs, should be obliged to comply with its provisions in a relatively short period of time.²⁹ However, TRIPS does not entirely extinguish or lose sight of the foundational values that have historically been behind the award of patents. Article 7 states that:

the protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users ... and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.

Article 8 (1) allows members to adopt measures ‘necessary to protect public health and nutrition’; Article 8(2) recognises the need for ‘appropriate measures ... to prevent the abuse of intellectual property rights’; Article 30 allows ‘limited exceptions to exclusive rights’; and Article 31 sets out conditions for use ‘without authorisation of the patent holder’ including in ‘situations of national emergency or extreme urgency’.

These are loopholes that ought to be exploited. For example, a case could be made that strict compliance with TRIPS will do exactly the opposite of what is envisaged by article 7: it will lead to the decimation and emigration of technology from developing countries such as India. However, the ability to open

and go through these windows is heavily dependent on the degree to which an emerging market or developing country is prepared to court other quasi-legal forms of sanction from industrialised economies. This was particularly the case in the years immediately succeeding TRIPS, when industrialised countries, egged on by lobbyists of the pharmaceutical industry, adopted a revanchist stance, contesting alleged violations of intellectual property rights in a number of countries simultaneously. Among countries that have felt the whip are Canada,³⁰ Thailand, Brazil,³¹ Ghana,³² the Philippines³³ and Kenya.

The drawn-out court battle between the South African government and the PMA is the most well known case.³⁴ Ironically, in this instance the complainants sought means outside dispute resolution channels of the WTO to press their arguments—suggesting perhaps a lack of confidence in their case. That may have been because many of the contested measures in South Africa's Medicines and Related Substances Control Amendment Act (90 of 1997) are standard practice in developed countries and, *prima facie*, in compliance with TRIPS. In effect, the legal action was an attempt by the PMA to try to use property rights in the *Constitution of the Republic of South Africa* to annex additional powers and safeguards for intellectual property (that are not part of TRIPS); to fill in some of the ambiguities in TRIPS, particularly its vagueness around 'parallel importation'; and to warn other developing countries off a similar path. Under a barrage of criticism that led to questioning by shareholders, politicians and prominent authors such as John Le Carré, the pharmaceutical companies withdrew their case against the South African government on 18 April 2001. Subsequently the US government also withdrew its WTO complaint against Brazil's Industrial Property Act. A temporary stalemate now exists.

In consequence of the one-sided manner in which TRIPS was drawn up—primarily taking into account the interests of the producers of inventions, rather than the public in need—a rearguard action has been fought to try to mitigate its impact. This has been led by a range of consumer, development and charity organisations, including the Consumer Project on Technology (CPT), Médecins Sans Frontières (MSF), Oxfam and TAC. This movement has been successful in stimulating an international debate on the morality of the international patent system in its current form. It argues that this system awards global market exclusivity for the manufacture and sale of patented medicines but does nothing to ensure global availability (the original equation). In fact, the effect is to further tie access to medicines to purchasing power, maintaining health and profitability on one side of the health curtain and paucity on the other. Three-quarters of the world's population, particularly those caught in the midst of epidemics of malaria, TB and HIV/AIDS are not served by this system.

These organisations argue not against patents or the principle of intellectual property *per se*, but warn that the system is being abused with horrendous consequences. Market exclusivity conferred on patent holders of essential medicines allows prices to be set that have no bearing on the actual costs of R&D or active ingredients. The prices yield substantial profits for healthy shareholders, but nothing for the sick. In the first world medical assurance and public health systems mean that consumers pay the price. In the third world it simply means that many essential medicines are unaffordable and treatable conditions go

without treatment.³⁵ Thus, according to Oxfam, in 2001–02 ‘around 11 million people, most of them in developing countries, will die from preventable and treatable infectious diseases. This is the equivalent to 30 000 deaths each day.’

Faced with unprecedented criticism and scrutiny the pharmaceutical companies have attempted to regain some ground. Initially this was through a high-publicity but low-delivery ‘Extended Access Initiative’ conducted under the auspices of UNAIDS. This was succeeded by various companies offering deep discounts on patented anti-HIV medicines directly to various African governments. It is important to ask why similar offers were not made in Asia, Eastern Europe or Latin America. Most recently there has been a campaign to publicise ‘empirical data’ that criticism of patents as a barrier to treatment access is misdirected.

The latter campaign draws heavily on an article authored by two academics, Amir Attaran and Lee-Gillespie White, suggesting that ‘patents and patent law are not a major barrier to treatment access in and of themselves’.³⁶ Attaran and White report on the findings of a study on the patent status of anti-retroviral drugs in Africa conducted in order to ‘test the hypothesis that patents are a leading barrier to widespread AIDS treatment in Africa’. They find that ‘of a theoretically possible 795 instances of patenting ... only 172 (21.6%) actually exist’. Although an interesting foray into the patent status of anti-retroviral drugs in Africa, the article unfortunately refuses to draw all the necessary conclusions from the empirical evidence it collates. For example, the authors provide a table of ‘Patent Coverage in Africa for Antiretroviral drugs, by Country’. Two patterns (other than the ones noted by the authors) emerge. The first is that in South Africa 13 of a possible 15 drugs have been patented. The second is that the drugs most commonly used in first-line ARV therapy (Combivir, Epivir, Zidovudine and Nevirapine), and those where significantly cheaper generic cocktails already exist, are the drugs most heavily patented across Africa. What should this tell the authors?

South Africa has the most serious HIV/AIDS epidemic in the world. Like many other parts of Africa it has millions of people mired in poverty. However, unlike many other sub-Saharan countries, it has a public and private healthcare infrastructure that could offer medicines and care to hundreds of thousands of people with AIDS—if they or the state could afford the medicine. It also has a substantial private health sector which purchases medicines at prices that are often higher than those in the USA and Europe, and which needs to be protected from generic competition to maintain its profitability. The result is the almost blanket patenting of anti-retroviral and other medicines: the consequence is the unaffordability of life-saving medicines.

Finally, despite protestations from the companies that anti-trust law prevents collaboration on price reductions, there is clearly method in the madness when it comes to blocking competition. The carpet bombing of South Africa and certain combinations of medicines with patents blocks generic suppliers for whom ‘entry into the South African market is necessary ... to reach the economies of scale (volume) needed for the most efficient production’.³⁷ On the basis of the above critique Attaran and White remain unconvincing.

Conclusion

The intense public discussion around drug access, patents and global health that has been described in this article has recently culminated in a temporary resolution of some of the issues and debates. In November 2001 the fourth Ministerial conference of the WTO in Doha produced a 'Ministerial Declaration on the TRIPS Agreement and Public Health'. Under pressure from activists and developing country governments, the US trade representative (to the chagrin of the pharmaceutical industry), broke with Switzerland and Japan and agreed to a Declaration that, while affirming the TRIPS agreement, recognised the 'concerns about its effects on prices'. Specifically it noted that:

(b) Each Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.

(c) Each Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.³⁸

The victory in Doha is an important milestone. It explicitly recognises that patents do push up prices and that there are remedies available to states. Further, it takes away any justification for self-censorship by governments who might argue that ambiguity about the meaning of Article 31 justifies holding back. In a similar fashion to the WTO, and as a consequence of the same pressures, the UN Committee on Economic, Social and Cultural Rights has also completed a policy statement on Human Rights and Intellectual Property.³⁹ These are important developments but their import must not be overestimated, particularly because pressures on countries to comply with unwritten rules of trade and economics remains.

This article has attempted to provide some evidence to show that global health is in a perilous state which will be difficult to remedy. Inaction not only costs hundreds of thousands of lives, but has political, social and economic consequences. The UNGASS Declaration, the formation of the Global Health Fund and other similar initiatives point in the right direction, but they cannot be allowed to inch forward with no tangible benefits over a number of years. Rather, there is a need for a new global compact on health, with a set of binding and justiciable rules similar to those that govern world trade. The starting point for such a compact is in the existing international instruments—the challenge is to compel compliance with them.

Several driving principles must be enunciated. Intellectual property is not an inalienable private right, like life or dignity or adequate health. It was a right that was created for a purpose, and that purpose is now being abused. Patents should be protected—up to a point. But patents cannot be protected on the basis of untested claims of drug development costs and veiled threats of an investment strike into new medicines.⁴⁰ If private industry cannot be encouraged to develop medicine relevant and affordable for three-quarters of the world's population, governments should intervene. This is not beyond the bounds of possibility. Faced with the threat of anthrax, both the US and Canadian governments

threatened compulsory licenses against Bayer in order to reduce the price of Ciprofloxacin. In a similar vein Paul Farmer quotes former US President Bill Clinton as justifying a budget of \$1.4 billion for chemical and biological 'attack preparedness' on the grounds that 'there is no market for the kind of things we have to develop; and if we are successful there never will be a market for them'.⁴¹

Finally, it is important that society should not lose sight of the fact that much is known of the diseases that plague the poor world. It is society and solidarity that is wanting—not science. HIV is a virus whose transmission can be prevented. Today AIDS is a condition that can be treated. Thus it is fitting to close with Dickens who, incensed by governmental inaction on a cholera epidemic that killed 20 000 people in England and Wales in 1854, hurriedly wrote an article for *Household Words* entitled 'To Working Men', where he threatened:

Let it come twice again, severely—the people advancing all the while in the knowledge that, humanly speaking, it is, like Typhus Fever in the mass, a preventable disease—and you will see such a shake in this country as never was seen on Earth since Samson pulled the Temple down upon his head.⁴²

Notes

- ¹ United Nations Economic and Social Council, Committee on Economic, Social and Cultural Rights, The right to the Highest Attainable Standard of Health: 11/08/2000 E/C. 12/2000/4; and CESCR General Comment 14, Substantive Issues Arising in the Implementation of the International Covenant on Economic, Social and Cultural Rights.
- ² J Mann, 'Article 1: dignity and health, the UDHR's revolutionary first article', *Health and Human Rights: An International Quarterly*, 3(2), 1998, pp 30–38. On p 38 Mann makes a suggestive comment that 'Future health professionals may look back at the current limited and narrow understanding of health and wonder how we could have missed seeing violations of dignity as sources of injury to well-being'.
- ³ World Health Organisation, *World Health Report 2000, Health Systems: Improving Performance*, Statistical Annex, pp 152–203.
- ⁴ *South Africa Demographic and Health Survey*, 1998, Department of Health, p 38. 'As expected, infant mortality has begun to increase with the impact of the HIV/AIDS epidemic.'
- ⁵ W Flanagan, K Koshnood & M Malinowska-Sempruch, 'Tangled epidemics: incarceration, tuberculosis and HIV in Russia', case study presented to 'Health, Law and Human Rights: Exploring the Connections, An International Cross-disciplinary Conference Honoring Jonathan Mann', American Society of Law, Medicine and Ethics, 29 September–1 October 2001; and P Farmer, *Infections and Inequalities: The Modern Plagues*, Berkely, CA: University of California Press, 2001.
- ⁶ D Saunders, L Biljmakers & M Bassett, 'Health and structural adjustment in Zimbabwe: implications for policy, human rights and ethics', paper presented to conference of American Society of Law, Medicine and Ethics, September/October 2001.
- ⁷ R Beyer, G Oppenheimer & J Colgrove, 'Health and human rights: old wine in new bottles?', paper presented to conference of American Society of Law, Medicine and Ethics, September/October 2001.
- ⁸ Universal Declaration of Human Rights, Article 25, in *The UNAIDS Guide to the United Nations Human Rights Machinery*, pp 27–29, emphasis added.
- ⁹ *Ibid.*, pp 43–47.
- ¹⁰ L Garrett, *The Coming Plague: Newly Emerging Diseases in a World Out of Balance*, London: Penguin, 1995, p 480.
- ¹¹ J Mann, S Gruskin, M Grodin & G Annas (Eds), 'Medicine and public health, ethics and human rights', in Mann, *Health and Human Rights: A Reader*, London: Routledge, 1999, pp 439–452. On p 440 Mann defines one of the differences between public health and medicine as 'in a sense, public health comes to you, while you go to the doctor'.
- ¹² See S R Benatar & P A Singer, 'A new look at international research ethics', *British Medical Journal*, 321, 2000, pp 824–826. 'Few commentators on research ethics have taken into consideration the injustice of 90% of all medical research being undertaken on those diseases that cause 10% of the global burden of disease', pp 824–826, citing Commission on Health Research for Development,

- Health Research: Essential to link equity in development*, Oxford: Oxford University Press, 1990. Note also: 'In the case of tuberculosis, for example, the last novel treatment was developed more than 30 years ago (t'Hoen 2000). Over the past two decades (1975–1996), less than 1% of more than 1200 new molecular entities sold worldwide were ear-marked for tropical diseases.' Farmer, *Infections and Inequalities*, p xxxii; and 'In the projected pharmaceutical market for 2002 Europe and North America represent 67% of total sales, while Africa and South East Asia together make up only 6.3% of the market'. Médecins Sans Frontières, 'The lack of medicines for tropical infectious diseases: a failure of the market or a public health failure?' (unpublished report) September 2000, p 4.
- ¹³ This was the main defence of the Minister of Health in Treatment Action Campaign and Others v Minister of Health and Others, High Court of South Africa, Transvaal Provincial Division, case 21182/01.
- ¹⁴ G Harris, 'Arms deal underpinned by outmoded thinking', *Business Day* (Johannesburg), 7 December 2001, p11.
- ¹⁵ Personal notes of presentation made to the annual general meeting of the Canadian HIV/AIDS Legal Network by Dr Pierre Lauzon, Centre de Recherche et d'Aide pour Narcomanes de Montréal, 23 September 2001.
- ¹⁶ 'The quality of health services in the region has already deteriorated significantly.' IMF, 'Providing health care to HIV patients in southern Africa', Policy Discussion Paper, October 2001, p 15; and 'The HIV/AIDS pandemic is creating a new wave of impoverishment ... If unchecked, it will reverse poverty gains dramatically and quickly.' UNDP, *Human Development Report*, Geneva: Oxford University Press, 1997, p 66.
- ¹⁷ Quoted in Garrett, *The Coming Plague*, p 475.
- ¹⁸ J Berger, 'Tripping over patents, AIDS, access to treatments and the manufacturing of scarcity', LLM thesis, University of Toronto, 2001, accessed from www.tac.org.za.
- ¹⁹ P Farmer, 'Pathologies of power: rethinking health and human rights', *Public Health Matters*, 89(10), pp 1486–1496. On p 1493 Farmer writes, 'Claims that we live in an era of limited resources fail to mention that these resources happen to be less limited now than ever before in human history. Arguing that it is too expensive to treat MDR-TB among prisoners in Russia, say, sounds nothing short of ludicrous when this world contains at least one individual worth more than \$60bn.'
- ²⁰ GlaxoSmithKline, 'European CPMP gives positive opinion on Glaxo Wellcome's new triple combination therapy for HIV', Press Archive, accessed from <http://corp.gsk.com/press>.
- ²¹ C Pérez-Casas, C Macé, D Berman & J Double, 'Accessing ARVs: Untangling the Web of Price Reductions for Developing Countries', *Médecins Sans Frontières*, 21 November 2001, online: <<http://www.accessmed-msf.org>>
- ²² Cipla Ltd, *Annual Report*, 2001, pp 10–11. Triomune is composed of three patented anti-retrovirals: d4T (Bristol Meyers Squibb), 3TC (GlaxoSmithKline) and Nevirapine (Boehringer Ingelheim).
- ²³ Compulsory licensing refers to the overriding of certain patent rights by the licensing of a competitor to produce and market a medicine that is still under patent. Compulsory licensing, in a limited number of circumstances and according to legally defined processes, is permissible in most countries.
- ²⁴ Accessed from www.wto.org.
- ²⁵ Charles Dickens, 'A Poor Man's Tale of A Patent', *Household Words*, 1850, accessed from www.underthesun.cc/classics/dickens/reprintedpieces. I am grateful to Bebe Loff of Monash University, Australia, for drawing my attention to this article.
- ²⁶ M P Ryan, *Knowledge Diplomacy: Global Competition and the Politics of Intellectual Property*, Washington, DC: Brookings Institution Press, 1998, p 9, quoting Charles E Lindblom, *Politics and the Markets: The World's Political Economic Systems*, New York: Basic Books, 1977.
- ²⁷ 'The creation of new international intellectual property law would need to be moved from the function-specific World Intellectual Property Organisation (WIPO) forum with its one-nation, one-vote decision making to the GAT forum with its economic power-based decision making.' Ryan, *Knowledge Diplomacy*, p 12.
- ²⁸ C Perez-Casas, D Berman & T Kasper, *HIV/AIDS Medicines Pricing Report: Setting Objectives: Is there a Political Will?*, MSF, July 2000. The report captures the extent of the price differentials between brand-name and generic medicines. For example: 'Nowadays, it costs an HIV/AIDS patient living in Thailand US\$9 per month to prevent cryptococcal meningitis, a life-threatening disease. But if this person happens to be in South Africa, he/she will pay US\$123 per month for the same product supplied by the public sector (nearly 14 times more). To purchase this same drug from the private sector would cost 71.4 times more' (p 12). The drug referred to is Pfizer's Diflucan.
- ²⁹ Transitional Arrangements in TRIPS (Articles 65 and 66) allowing developing and least-developed country members up to 10 years to apply the provisions of the agreement.
- ³⁰ In 2000 the European Commission filed a complaint with the WTO alleging that aspects of Canada's Patent Act violated the requirements of TRIPS. The EC opposed that part of the law that allowed generic drug manufacturers to stockpile their generic version of a patented medicine six months

before the patent expired in order to be able to quickly enter the market. For a summary of the case, see R Elliott, 'What's TRIPS got to do with it? And why should Canadians care?', in *Human Rights, Global Responsibility and Access to Treatments in the Developing World*, September 2001, accessed from www.aidslaw.ca.

- ³¹ In 2000 the USA filed a complaint with the WTO against Brazil's Industrial Property Act allowing compulsory licensing in the absence of 'local working' of a patent.
- ³² M Schoofs, 'Glaxo attempts to block access to generic drugs in Ghana', *Wall Street Journal*, 1 December 2000. In a letter from the Chief Executive of GlaxoSmithKline in South Africa to the AIDS Consortium, an NGO, dated 19 January 2001, it is stated 'our letter was intended to alert Cipla to the existence of our patents on lamivudine and zidovudine in Ghana'.
- ³³ In November 2000 the Pharmaceutical and Healthcare Association of the Philippines (a federation of multinational pharmaceutical companies) sought a court order restraining the Philippine government from parallel importation of cheaper patented medicines from India. However, this was denied by the regional trial court and the government proceeded with the purchase.
- ³⁴ M Heywood, 'Debunking conglomeratalk: a case study of the amicus curiae as an instrument for advocacy, investigation and mobilisation' in *Law, Democracy and Development*, 2002 (forthcoming).
- ³⁵ See Oxfam, *Patent Injustice: How World Trade Rules Threaten the Health of Poor People*, Oxford: Oxfam, 2001; Oxfam, *Fatal Side Effects: Medicine Patents Under the Microscope*, Oxford: Oxfam, 2001; and TAC affidavits as amicus curiae in the PMA case at www.tac.org.za.
- ³⁶ A Attaran & L Gillespie-White, 'Do patents for anti-retroviral drugs constrain access to AIDS treatment in Africa?', *Journal of the American Medical Association*, 286(15), 2001, pp 1886–1892.
- ³⁷ Consumer Project on Technology *et al*, 'Comment on the Attaran/Gillespie-White and PhRMA surveys of patents on anti-retroviral drugs in Africa', October 2001, www.cpt@ch.org
- ³⁸ Accessed from http://www-chil.wto-ministerial.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm, 11 December 2001.
- ³⁹ Personal communication with Audrey Chapman, 11 December 2001.
- ⁴⁰ At paragraph 7.2.1.4 of the Answering Affidavit of the PMA to the allegations made by the Treatment Action Campaign, Myreana Deeb, the CEO and deponent, made the following infamous threat: 'If no encouragement in terms of reasonable financial returns on the required investment is to be allowed to the research-based multi-national pharmaceutical industry, the motivation for the search for a solution for this disease will disappear. Then the only remaining scenario is that the disease will find its own end: the funeral of the very last carrier of the virus.'
- ⁴¹ P Farmer, *Infections and Inequalities*, p xiii.
- ⁴² C Dickens, 'To Working Men', *Household Words*, 7 October 1854. Quoted in P Ackroyd, *Dickens*, London: Sinclair Stevenson, 1990, p 709.