



Preface by Sir John Sulston Co-founder of the Human Genome Project

At a time when new technology has such potential to contribute to human welfare, and has also become the most important determinant of competitiveness in global markets, it is very disturbing that the monopoly rights of the producers of technology are being strengthened. I am therefore very pleased that Oxfam, with its extensive development experience, has stepped into this complex technical field by providing its own penetrating account of how strengthened patent rules will affect the health of ordinary people, particularly those living in poor countries.

Oxfam's briefing paper shows how new global patent rules, introduced by the World Trade Organisation, will raise the costs of vital medicines, with potentially disastrous implications for poor countries. In brief, these rules require all countries to provide patent protection for a minimum of 20 years for inventions in all fields of technology, including medicines.

As the report points out, in the pharmaceutical sector the winners will be the large northern-based transnational companies which, as a result of the lengthened patent protection provided by WTO rules, will be able to sell their new medicines at higher prices. The losers are likely to be the millions of people who will be unable to afford vital new medicines, and hard-pressed government health services. This situation will undermine efforts to increase productivity and eradicate poverty, and will result in a widening of the gap between rich and poor nations.

Patents have an important role to play in stimulating investment and innovation. But any patent system has to balance the need to reward inventors with the greater public interest for people to benefit from new inventions. Oxfam's paper makes a compelling case that current WTO rules, as a result of corporate lobbying, sacrifice public health for private profit. It also points out the extraordinary anomaly whereby the WTO, an organisation charged with developing rules for 'free trade', is providing a legal framework for the development of corporate monopolies.

I hope this report will convince governments and companies of the urgent need to review and revise global patent rules in order to prevent adverse impact on health and development. While the full effects of WTO patent rules may not be seen for some time, this report shows that there is enough evidence to warrant action now.



## Executive summary

Oxfam is campaigning to cut the cost of medicines for poor people. The campaign is being launched now because global trade rules - in the shape of the World Trade Organisation's agreement on intellectual property rights - are being implemented which threaten to make the problem much worse in the future.

Public health in industrialised countries is being transformed by breathtaking medical advances. Major breakthroughs in the detection and treatment of disease are increasing life-expectancy and reducing vulnerability to sickness. But over the course of the next year, around 11 million people, most of them in developing countries, will die from preventable and treatable infectious diseases. This is the equivalent of 30,000 deaths each day. Almost half of the victims will be children under the age of five. The vast majority will be poor. Many millions more will suffer protracted bouts of sickness and disability, with devastating impact on levels of poverty and vulnerability.

The health gap between rich and poor countries is reinforcing wider inequalities in income and opportunity, and undermining efforts to meet internationally agreed human development targets.

Much of the premature death and disability associated with infectious disease could be avoided, and the health gap closed, if poor people had access to affordable medicines. Yet those most in need are least able to afford treatment. Across the developing world, household poverty, inadequate public spending, and weak public-health infrastructures combine to place effective treatment beyond the means of the poor. According to the World Health Organisation (WHO), some two billion people in developing countries lack regular access to vital medicines. Moreover, infectious diseases do not respect national borders. The wider international community will also suffer from problems associated with the failure to meet public-health challenges in poor countries, such as slow growth and increased poverty.

**This Briefing Paper is prompted by a concern that international trade rules, dictated by Northern governments and pharmaceutical companies, and administered under the auspices of the World Trade Organisation (WTO), will further diminish the access of poor people to vital medicines. The most immediate victims will be the poor, but rich countries will not be immune to the consequences.** It is one of three papers produced by Oxfam as part of its Cut the Cost campaign. The other two are: Dare to Lead - a challenge to GlaxoSmithKline and Fatal Side Effects: Medicine Patents under the Microscope - a technical paper on this issue. Both are available on Oxfam's website.

### Background

Under the WTO's intellectual property (IP) regime, all member countries are required to provide exclusive marketing rights to holders of patents on pharmaceutical products for a period of at least twenty years. By restricting the right of governments to allow the production, marketing, and import of low-cost copies of patented medicines (called generic drugs), the WTO's rules will restrict competition, increase prices, and further reduce the already limited access of poor people to vital medicines.

While the precise effects of the new rules will vary across countries, average price increases could be in the range of 200-300 per cent for many low-income countries, and higher for some key medicines.

This is not a distant threat. The application of strengthened patent rules to medical products is already causing serious problems, notably in relation to the treatment of HIV/AIDS.



**Patented versions of anti-retroviral therapies which are used to keep HIV in check, and other drugs effective against the diseases which accompany HIV and cause opportunistic infections, typically cost between 3 and 15 times as much as their generic equivalents.**

In countries with large numbers of HIV-sufferers and chronically over-stretched health budgets, price differentials can mean the exclusion of millions of people from effective treatment.

The problem extends beyond HIV. **Prices for non-patented (generic) versions of antibiotics used to treat major childhood killers such as diarrhoea and chest infections are often marketed at prices less than one-eighth of those for equivalent patented products.**

The next generation of medicines which could be used to combat these and other infectious diseases will, if the existing WTO rules persist, be marketed in developing countries at prices which reflect the monopolistic pricing opportunities provided through patents.

**At a time when millions of lives are at risk from newly-virulent diseases, and from the increasing drug resistance to old killers, trade rules threaten to make basic medicines even less affordable to the poor.**

WTO rules provide limited public-health safeguards, especially in the case of national health emergencies. These are hedged in by onerous conditions and, in practice, efforts to apply these measures have been fiercely contested by pharmaceutical companies, often with the backing of Northern governments.

It is hard to argue that HIV/AIDS does not represent a national emergency in South Africa, where it is projected to reduce life-expectancy by 20 years by 2010, or in Thailand, where there are almost one million sufferers. Yet in both cases, efforts to provide cheap generic medicines have

been met with legal challenges mounted by formidably powerful corporations. In Kenya, one quarter of the adult population is HIV-positive, but fewer than two per cent receive anti-retroviral treatment. **If the country were able to import the drug fluconazole, used in the treatment of cryptococcal meningitis (an opportunistic infection associated with HIV/AIDS), from Thailand, it could reduce the annual cost of treatment from over US\$3000 to US\$104.**

However, the patent holder for the drug, the Pfizer corporation, applied pressure to stop such imports taking place.

More recently, pharmaceutical giant GlaxoSmithKline (GSK) has challenged importers of medical products in Ghana and Uganda. Their 'crime': seeking to import copies of the firm's patented Combivir, an anti-retroviral for the treatment of HIV/AIDS, at half the price of the brand-name product.

These are not isolated cases. The implementation of WTO patent rules is taking place against the backdrop of a sustained campaign led by the pharmaceutical industry which may well erode the public-health protection offered by safeguard provisions. This industry campaign has been led by the Pharmaceutical Research and Manufacturers of America (PhRMA), one of the world's most politically influential and well-financed industrial lobbies. The primary source of PhRMA's power is its influence over the office of the United States Trade Representative (USTR), which has repeatedly backed its claims with the threat of trade sanctions under 'Section 301' of national trade legislation.

The influence of PhRMA threatens the credibility of the WTO, with implications for the functioning of the wider multilateral trading system. The use of the WTO to advance the interests of powerful companies will also further erode the credibility of global institutions at a time when effective multi-



lateralism is desperately needed to address problems of poverty and inequality, and to underpin shared prosperity.

### **The cost of illness: why prices matter**

The affordability of medicines is only one of the problems facing poor countries. Inadequate and inequitable public spending on health infrastructure, weak planning, failure to prioritise preventative interventions, and ineffective service provision are also contributory factors. But the price of basic medicines is a vital factor in determining public health.

The price of medicines is a critical issue in rich countries as well as in poor. In Britain and the United States, the budget implications of escalating drugs prices are a matter of mounting political concern. But it is the poorest countries, where budget resources are more limited, and where household poverty is most widespread, that face the gravest threat from rising drugs prices.

Most health spending in the poorest countries comes directly out of household budgets, rather than through national health budgets or pre-paid insurance schemes. For the poor, the cost of treating sickness is often prohibitive. In Zambia, where two-thirds of rural households live below the poverty line, it costs one such household US\$9 to treat a single case of childhood pneumonia – an amount equivalent to half the family's monthly income. The high cost of treatment relative to income can result in poor households either delaying or not seeking treatment. It can also lead to the diversion of expenditure from other vital areas such as food and education.

### **The WTO and drugs: the rules are loaded against the poor**

The WTO's Agreement on Trade Related Intellectual Property Rights (TRIPS) establishes minimum standards for intellectual property

protection, including the right to exclusively market a patented product for at least 20 years. Some Northern governments are using bilateral and regional trade agreements to negotiate even more stringent protection for patents under so-called 'TRIPS plus' agreements.

WTO rules recognise the potential conflict between public-health interests and the private interest of patent holders. Under Article 31 of the Agreement, governments can issue compulsory licences to authorise production without the consent of patent holders, subject to adequate compensation. Another measure open to governments is that of parallel importing, whereby governments allow the importation of a patented product which is marketed elsewhere at prices lower than those in the domestic market.

These safeguards should be strengthened. There is a need to clarify and broaden the criteria for introducing compulsory licences, and to diminish the burden of proof currently placed on governments seeking to establish public-health threats as grounds for compulsory licensing. In the event of a dispute, patent holders should be required to prove that there is no threat to public health from the strict application of their patent privileges. Even with less onerous conditions for compulsory licensing, countries with limited production capacity or small internal markets will find it impossible to obtain the required drug at an affordable price, unless there is a larger country which is producing it under a compulsory licence and which is willing and able to export it to them.

The deeper problem lies in the unwarranted political influence of pharmaceutical corporations which leads to a subordination of trade policy to corporate goals, notably in the USA. In the course of the past year, a large number of developing countries, which have failed to strengthen patent rules on terms dictated by PhRMA, have been threatened with trade sanctions:



- **India** has been placed on the hit list for trade sanctions for failing to include highly restrictive compulsory licensing conditions in national legislation, and for allowing generic companies to export copies of patented drugs. These exports are a major source of basic medicines for low-income developing countries.

- The US has threatened trade sanctions against the **Dominican Republic**, including the withdrawal of trade preferences for textiles, for failing to comply with the demands of PhRMA members. Despite the small size of the local market, the country has been targeted by PhRMA, which claims that it represents a bad example that others will follow.

- WTO disputes have been initiated against **Argentina** and **Brazil**. Both countries are accused of failing to incorporate highly restrictive conditions for the granting of compulsory licences into national legislation.

In each case, the target has been national legislation authorising production of low-cost equivalents of patented drugs to meet public-health needs. Governments in Europe may have been less public in their threats, but they have silently colluded in supporting the coercive trade diplomacy practised by the United States.

PhRMA's political influence comes at a price. Between 1997 and 1999, PhRMA's members spent US\$236m lobbying Congress and the executive branch of government. Another US\$14m was provided to political parties in 1999 alone. Approximately two-thirds of corporate investment in political lobbying in the USA is directed towards the Republican Party, raising concerns about corporate influence over the new Administration.

**Various polite formulations and legalistic arguments can be used to explain what is happening in the name of IP protection.**

**But the truth is that corporate self-interest is being placed before people's lives.**

### **Patents and prices: the threat to public health**

Most developing countries have in the past avoided stringent patent regimes on medicines in the interests of public health. Highly sophisticated generic industries have emerged with a specialisation in the development of low-cost equivalents of expensive patented medicines for low-income populations. Countries such as India, Thailand, Egypt, and Brazil have succeeded not just in reducing their dependence on imported medicines, but also in developing their capacity to export them. Across sub-Saharan Africa, most front-line medicines used in the treatment of infectious diseases are imported from generic-drugs suppliers. These drugs are typically available at prices ranging between one-fifth and one-tenth of those for patented brand-name products.

**Because generic-drugs industries are able to market products at a fraction of the costs associated with patented brands, they provide a lifeline to low-income households. The WTO agreement on intellectual property rights threatens to cut that lifeline.**

Price comparisons between Pakistan, which has traditionally provided strong product patent protection, and India, which has one of the world's strongest generic-drugs industries, are instructive. They show that prices for ciprofloxacin, a safe anti-infective medicine used in the treatment of illnesses such as resistant bloody diarrhoea in children, are up to eight times more costly in Pakistan.

Price increases resulting from the extension of exclusive marketing rights will have grave consequences for public health in developing countries. Infectious diseases that were once

relatively easily curable with simple antibiotics are becoming increasingly drug-resistant. Old killers such as malaria, tuberculosis, bloody diarrhoea, and respiratory infections – a group of diseases that cost millions of lives each year – are proving increasingly difficult to treat.

Improved access to effective and affordable medicines is essential if these threats are to be addressed. But the danger is that use of the next generation of drugs needed to protect public health will be restricted, either by new patent protection or by the extension of old patent rights.

#### **Research and development: the market reality**

Pharmaceutical companies and Northern governments justify reinforced patent protection under the WTO as necessary to stimulate investment in finding cures for infectious diseases in developing countries. They also argue that the exclusive marketing rights provided by patents represent a legitimate reward for the high levels of investment and risk associated with developing new drugs.

As in other sectors, patents are useful in stimulating investment in pharmaceutical research and development (R&D), but the real debate is about the duration and scope of patent protection. As *The Economist* has argued, twenty years is an excessively long period over which to entrench monopoly rights, especially in a sector already characterised by high profit margins. Moreover, the patent system itself is subject to serious misuse. Companies have developed a high level of expertise in prolonging the life of patents through minor modifications which may not amount to genuine scientific invention. And while the cost of developing new medicines is high, in many cases part of this is covered by public funds and tax breaks.

The claim that reinforced patent protection will stimulate large-scale investment in finding cures for diseases of the poor is at best speculative, and at worst specious. **Only ten per cent of global R&D is directed towards illnesses that account for 90 per cent of the worldwide disease burden.** The problem is rooted in poverty, not in industrial incentive structures. Simply stated, developing countries are too poor, and their markets too small, to induce investment on the scale required. In the global health market, long-term ailments of the rich world, and medicines for afflictions such as high cholesterol and obesity, make for healthy profit; diseases of the poor world do not.

If the R&D gap is to be closed, the initiative will have to come from the public sector, with the private sector playing a strong but supportive role. That is why the international community needs to develop a global fund aimed at supporting a network of public research institutes, dedicated to work on infectious diseases in poor countries. There is evidence that public investment can succeed in overcoming market disincentives for investment in public goods, as witnessed by the Human Genome Project. Moreover, the technologies that underpinned the Green Revolution in agriculture were the result of investment by private foundations and governments, with the private sector playing an important but limited role.

#### **The case for reform: beyond corporate philanthropy**

The pharmaceutical industry rejects the argument that lower levels of patent protection are vital to the provision of affordable medicine. It claims that public-private initiatives, which may include agreements on 'tiered pricing' (with companies supplying medicines to poor countries at lower prices), are the appropriate response.



Such public-private partnerships have an important role to play in closing the health divide between rich and poor countries. Several major pharmaceutical corporations are supporting international initiatives either by donating drugs or by subsidising drugs provision, often receiving generous tax benefits in return. There are long-standing initiatives in place for controlling malaria, tuberculosis, and river blindness.

Pharmaceutical companies cite such agreements as evidence that strict patent protection under the WTO is compatible with socially responsible marketing. Reality is more prosaic. The main problem with these initiatives is that drugs are often made available in limited quantities, and at prices which compare unfavourably with those for generic-equivalent products.

During 2000, these initiatives were supplemented by an agreement between UNAIDS and five pharmaceutical companies (Glaxo Wellcome (GW), Merck, Hoffman-La Roche, Bristol-Myers Squibb, and Boehringer Ingelheim) to improve access to treatment for HIV-positive people in developing countries. Under this agreement, the companies will provide anti-retroviral products at significant discounts as part of a national AIDS plan.

Nevertheless, it has been slow to implement – only two countries have signed up so far – and many African governments continue to argue that the waiving of patent rights on life-saving drugs would be a far more effective way of bringing down prices.

**In effect, corporations in the pharmaceutical sector are offering islands of philanthropy, while promoting a global patents system which would enhance their profitability, but which could also consign millions to unnecessary suffering. Commercial self-interest and corporate philanthropy are pulling in different directions.**

## Recommendations

Public pressure and political challenges mounted by governments in developing countries are starting to influence the debate on the application of patent rules to pharmaceutical products. The British Government, in its recent White Paper on Globalisation, announced that it would establish a commission to look at how IP rules could be reformed to better protect the interests of the poor. This is an encouraging step in the right direction. But research and reflection is no substitute for substantive action in the following areas.

### 1. **Change trade rules to cut the cost of vital medicines.**

Developing countries should retain the right to produce, market, import, and export affordable medicines. The principles of patent protection set out in the WTO agreement should not be used in ways which inhibit this right. Provisions in the TRIPS agreement to safeguard public health through compulsory licensing and parallel importing should be strengthened, and the scope for legal challenges by patent holders limited. Under no circumstances should bilateral and regional economic agreements be used to ratchet up patent protection. The duration of patent protection on pharmaceutical products should be shortened and the scope of protection limited.

Consistent with international human rights obligations, it should be agreed that the health crisis in many poor countries constitutes a national emergency. Under Article 31, WTO members may waive the requirement to seek voluntary licences in cases of such emergencies or other extreme circumstances. This would allow governments to address local health needs without going through arduous and prolonged negotiations on patents.

**2: End rich-country bullying in negotiations on patents.**

The WTO should prevent industrialised countries from demanding high levels of patent protection in developing countries through the threat or use of unilateral trade sanctions or legal challenges. Section 301 of US trade legislation should be repealed with immediate effect.

**3: Invest in a research fund for diseases of the poor.**

Given the lack of commercial interest in researching infectious diseases in developing countries, a US\$5bn international fund should be set up under the auspices of the WHO to support a global network of public research institutions dedicated to developing new medicines and vaccines. Public investment and international co-operation, rather than extended patent rights, hold the key to narrowing the global health divide.

**4: Pharmaceutical giants should cut the cost of key medicines to developing countries.**

Pharmaceutical companies should reduce the price of key medicines in developing countries so that they are affordable to the poor. Prices should be determined as part of an international and transparent system of equitable pricing, developed in conjunction with the WHO, with price differentials based on the Human Development Index and on a country's ability to pay. As the world's largest pharmaceutical company, GSK should lead by good example, by making the drug Malarone available to developing countries at a price no higher than existing malaria treatments.

**5: Pharmaceutical giants should balance public health and their patent claims in poor countries.**

Pharmaceutical companies should exercise social responsibility with respect to their patent

claims. They should not seek to enforce patent claims in the poorest countries on drugs essential to public health.

**6: Assess the impact of stronger patents on the health of poor people.**

The forthcoming review of TRIPS should include a comprehensive assessment of its effects on the affordability and availability of medicines in developing countries. The review should be supported by independent studies by the WHO and other relevant international organisations, in consultation with governments and public-interest groups.

**7: Stop patent protection on bio-piracy.**

WTO rules should be amended to prevent bio-piracy. As a first step, the TRIPS regime should be harmonised with the Convention on Biodiversity, with patent holders required to disclose the origin of biological materials and to demonstrate prior informed consent of the original holders of the knowledge applied in the development of patented products.

**8: An international fund should be established to subsidise drug purchases and delivery systems in the poorest countries.**

An international fund for medicines will offer long-term support and will remove the arbitrariness and uncertainty of bilateral drug donations by companies. It could also reduce costs by organising international tenders for bulk purchase. Aid funds are also required to support the all-important delivery systems, which must be properly integrated into national health services. The decline in aid for health services in developing countries should be reversed.



## Background

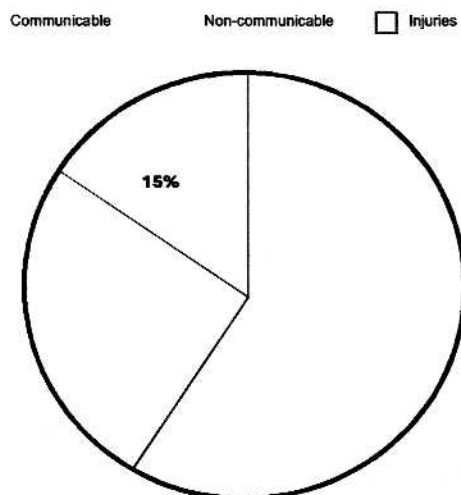
We have entered the twenty-first century in the midst of breathtaking medical advances. Computer technologies, new diagnostic and surgical techniques, and progress in bio-medical sciences have combined to produce major breakthroughs in the detection and treatment of killer diseases. The unlocking of the human genome holds out the prospect of unparalleled progress in the treatment of many diseases. Yet the advance in public health is partial, with the benefits heavily concentrated on a minority of the world's population living in rich countries. The vicious cycle of poverty and ill-health that is destroying lives on a vast scale in poor countries remains intact.

This year, 11 million people, mostly living in developing countries, will die from infectious diseases such as pneumonia, tuberculosis, measles, and diarrhoea (Figures 1 and 2). Almost half of them will be children who have not reached their fifth birthday. The overwhelming majority of the victims will be poor.

The widening health divide between rich and poor countries provides a stark reminder of the inequalities that have accompanied globalisation.

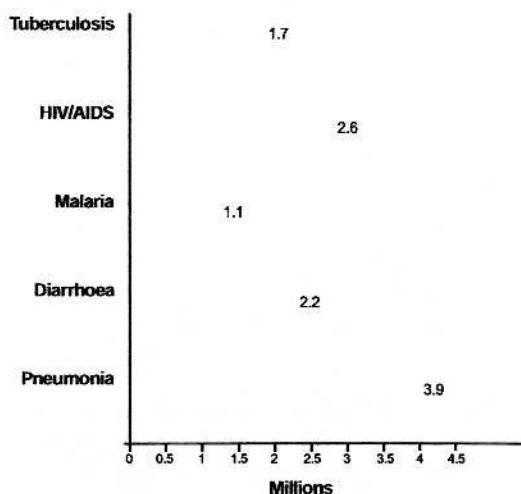
Rising prosperity and human suffering are marching hand in hand. Governments in the industrialised world seldom miss an opportunity at high-level UN summits to stress their commitment to ambitious targets for poverty reduction, and to the achievement of 'globalisation with a human face'. But the gap between rhetoric and the real policy choices taken by these governments is widening – and nowhere more so than in the setting of world trade rules.

Figure 1: Causes of death and disability among the global poor



Source: WHO World Health report 2000, Statistical Annexes

Figure 2: Major causes of death in poor countries



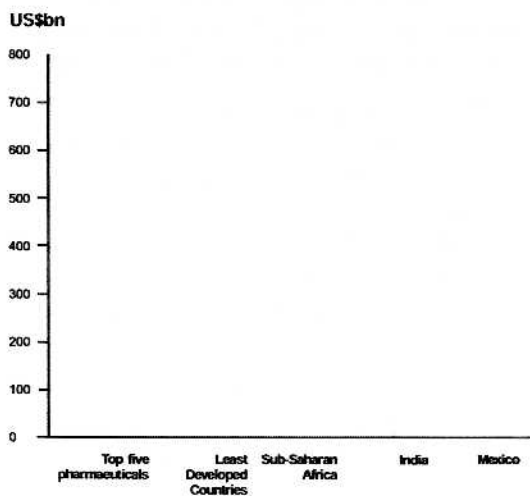
Source: WHO World Health report 2000, Statistical Annexes

### The World Trade Organisation (WTO) and the health divide

This Briefing Paper has been prompted by Oxfam's growing concern over the public-health implications of intellectual property (IP) rules enshrined in the WTO. These rules, driven through the WTO by the United States, Europe, and Japan, are the product of an intensive lobbying exercise led by the world's largest and most powerful pharmaceutical companies: Merck, Pfizer, Glaxo Wellcome (GW), SmithKline Beecham (SB), and Eli Lilly. The financial power of these companies is enormous. Taken collectively, the largest five drugs companies have a market capitalisation greater than the economies of Mexico or India – and twice the GNP of sub-Saharan Africa (Figure 3).

Financial power has been converted into political influence. These pharmaceutical companies have helped lead the way to WTO rules that will increase the profits accruing to drugs patent holders: namely, themselves and their shareholders. Northern transnational corporations (TNCs) account for over 90 per cent of global patents on pharmaceutical products.

Figure 3: Comparison between market capital of top five pharmaceutical companies and GNP of developing countries



Source: Human Development Report 2000; FT500, 4 May 2000

The WTO's rules have dramatically strengthened the exclusive marketing rights of the inventors of new drugs. The period of patent protection has been extended to at least 20 years. During this period, potential competitors are prohibited from producing and marketing cheap equivalents of these products. From 2000, most developing countries are required to ensure that their national legislation protects the IP of foreign pharmaceutical companies in this way, or face the prospect of WTO-sponsored trade sanctions. Some countries are allowed more time to become compliant, but all have to grant provisional 'market exclusivity' for patents filed after 1995, so the rules are effectively in place now.

Complex as the WTO rules may be, the likely outcome is relatively simple. They will raise the price of medicines, including those needed for the treatment of poverty-related illness. Generic-drugs industries, which specialise in developing low-cost copies of patented drugs for low-income populations, will be prevented from producing and exporting. The major source of competition and downward price pressure in domestic drugs markets will be eliminated.

The WTO patent regime for pharmaceutical products is not a future threat. It has already inflicted enormous damage. During 1998 and 1999, the South African government faced the constant threat of trade sanctions from the USA. Its 'crime': amending its law to allow importation of copies of patented anti-retroviral HIV/AIDS drugs from generic-drugs suppliers. The copies cost less than one-half of the patented versions. More recently, GlaxoSmithKline (GSK) has challenged the legality of imports of anti-HIV/AIDS generic drugs to Ghana and Uganda from India. HIV/AIDS affects over 25 million people in sub-Saharan Africa alone.

The threat of trade sanctions has played a pivotal role in the development and implementation of the new WTO regime. Following complaints from the Pharmaceutical Research and Manufacturers of America (PhRMA), an industry body representing the world's largest pharmaceutical companies,



the Government of the United States has threatened unilateral trade sanctions against over 30 countries under the 'Special 301' provision of the country's trade law. Countries such as India, Egypt, and Argentina, all of which have strong generic-drugs industries, have been among the prime targets. Apart from its dubious legality in terms of WTO principles, the use of 'Special 301' has raised disturbing questions about corporate influence over US trade policy and, via this channel, over WTO rules.

#### **Future implications**

The threat goes beyond HIV/AIDS. The next generation of front-line drugs which could treat major killers such as malaria, pneumonia, and diarrhoea (which collectively claim almost seven million lives a year) and tuberculosis (16 million cases a year), will be patented. There will be no inexpensive generic versions available until after patent expiry – which under WTO rules is at least 20 years from the filing date. Past evidence on price differentials between patented and generic drugs suggests that the effect on prices will be dramatic. In Thailand, the introduction of a generic competition reduced the cost of drugs for the treatment of meningitis by a factor of 14. Generic drugs for the treatment of resistant shigella, a major cause of bloody diarrhoea, are sold in India at one-eighth of the price of patented equivalents.

Increased prices resulting from patent protection will intensify the pressures faced by the poorest households in dealing with sickness. At a time when diseases such as HIV/AIDS and drug-resistant variants of old killers are placing millions of lives at risk, world trade rules are threatening to raise the costs of vital drugs.

The central problem with the agreement on patents negotiated at the WTO is that, in its implementation, it is placing corporate profit before human welfare. Governments of the industrialised world – including those in the EU – have colluded

in developing a set of trade rules which threatens to further restrict the access of poor people to medicines. This will lead to greater sickness, suffering, and premature death on a massive scale. Their actions raise fundamental questions about global governance, and about democracy and accountability in multilateral organisations such as the WTO. They also rest uneasily with pious declarations about internationally agreed health targets.

Failure to fundamentally reform the WTO's patent rules will threaten the lives of some of the world's most vulnerable people by reinforcing the lethal interaction between poverty and ill-health. But the costs of ill-health do not stop at the household. Widespread sickness acts as a brake on economic growth, and denies children the opportunity to realise their potential in education. While poor households will bear the brunt of these costs, the consequences will extend beyond national borders. No country is immune to the spread of infectious disease, or to the consequences of the poverty and inequality generated by ill-health. That is why the entire international community has a responsibility to ensure that world trade rules promote public health.

This Briefing Paper is organised as follows. Part 1 looks at the global health divide and explains why the price of medicines is of such vital concern to poor people. The fact that most poor people pay for health care directly out of their own pockets is central to the potential threat posed by WTO patent provisions. Part 2 explains the WTO's rules on patents, and shows how the application of patents raises the price of treatment for diseases affecting the poor. It also looks at the undue influence of pharmaceutical companies on the trade policies of industrialised countries and on the WTO. Part 3 reviews some of the broader arguments for and against patents and their application to pharmaceutical products. Part 4 sets out an agenda for reform.

## 1 The cost of illness: why prices matter

**'If you don't have money today, your disease will take you to your grave.'**

Ghanaian women

**'How can poor people afford medicine when they cannot feed their children. The rich can buy health treatment and drugs. For the poor, drugs are an unaffordable luxury.'**

Zambian health worker

**'For poor people sickness is a constant fear. It means that you will fall into debt. It is hard for us to buy the drugs we need to treat our children when they have a fever.'**

Vietnamese farmer

Much of the debate about medicines and patents at the WTO has been dominated by lawyers and economists, many of them working for powerful drugs companies. The terms of the debate have been highly technical. People – notably poor people – and public-health concerns have been conspicuous by their absence from the agenda.

The omission is unfortunate because the global health context in which WTO rules will operate is important. Life-expectancy in developing countries is 13 years shorter than in developed countries, and child mortality rates are ten times higher. In much of sub-Saharan Africa, almost one in five children die before the age of five. While health indicators are improving in parts of the developing world, the 2015 goal of reducing child deaths by three-quarters will be missed by a wide margin if current trends continue, especially in South Asia and sub-Saharan Africa.

Infectious disease threatens everyone, but the poor are most at risk. Communicable diseases

account for around two-thirds of premature death and disability in poor countries, compared with some ten per cent in industrialised countries. Within poor countries it is poor households that are most at risk. Poverty, poor nutrition, and inadequate access to clean water mean that their members are more likely to fall ill – and when they fall ill they have more limited access to treatment.

In India, tuberculosis affects 12 million people, but its prevalence is four times as high among the poorest fifth of the population as among the richest fifth. Rates of acute respiratory infection are twice as high, yet poor people are 20 per cent less likely to seek formal medical care. One reason for this discrepancy is that poor people know that they will be unable to afford the cost of treatment. Evidence from poverty assessments across the developing world shows that the high price of drugs is one of the main factors causing poor households either to avoid seeking treatment or to cut their treatment short.



**The price of health: the cost of medicines and the poor**

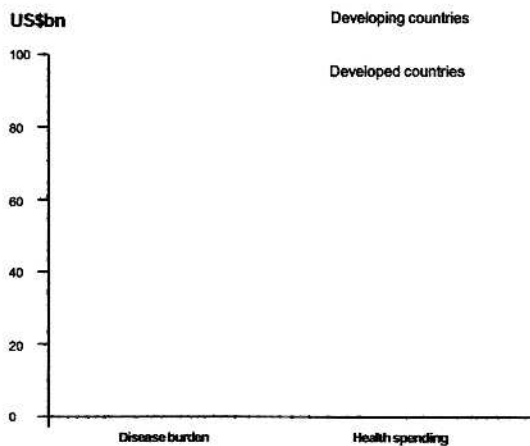
Any analysis of the potential impact of the WTO's IP rules has to start with the recognition of a simple fact: namely, millions of the world's poorest people are unable to afford the cost of treating the infectious diseases which blight their lives. This problem, which is rooted in a combination of household poverty, inadequate public provision, and high prices, means that any increase in the price of vital medicines will have the effect of adding to the ranks of those already excluded from access to adequate health care.

Aneurin Bevan, the founder of the British National Health Service, wrote: 'the essence of a satisfactory health service is that the rich and the poor are treated alike, that poverty is not a disability, and wealth is not an advantage'.

He would have been horrified by data on the state of the global health system. Each year the world spends seven per cent of its GDP on health, but resources are inversely related to need (Figure 4). Poor countries account for over 80 per cent of the global burden of disease, but only ten per cent of health spending. Sub-Saharan Africa, the region with the highest rates of child mortality and lowest life-expectancy, accounts for one per cent of total health spending.

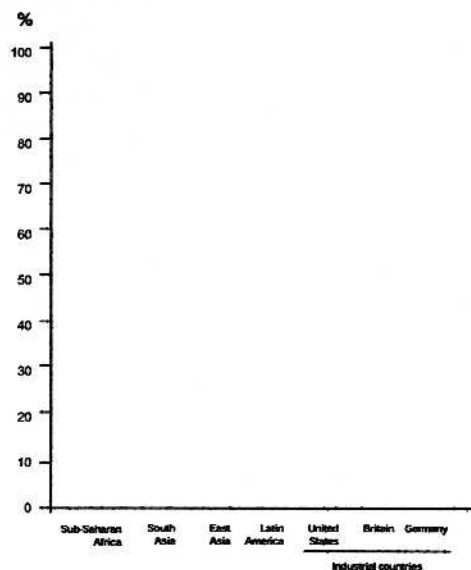
The inequity does not stop there. In rich countries, health-service provision is dominated by public spending, or, as in the case of the USA, by pre-paid private insurance. In poor countries (Figure 5), people meet the cost of sickness – including the purchase of drugs – out of their own pockets. This is a reflection of the inadequacy of public investment and the inability of poor people to afford private health insurance.

**Figure 4: Distribution of global disease burden and health spending**



Source: The Burden of Disease Among the Global Poor, World Bank 2000

**Figure 5: Health Spending in selected regions and countries: private as a proportion of the total**

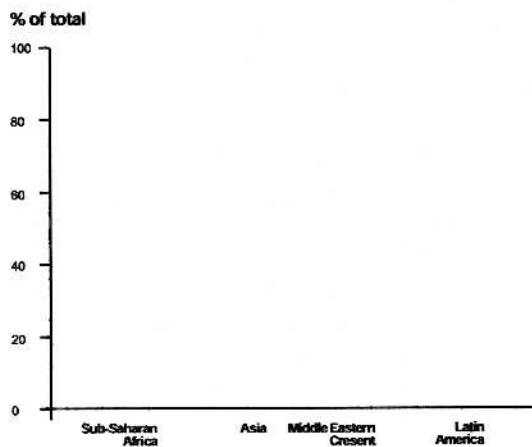


Source: World Bank and Health Organisation

There is a paradox at the heart of the global health system in that financial provision is inversely related to need. Rich countries accounting for a small proportion of the global disease burden not only spend much more on their health, but governments account for a much larger proportion of this. In Britain, health spending is approximately US\$1,193 per person per annum, with households paying only three per cent of this amount out of their own pockets. Health spending per person in India is only US\$23, but 84 per cent of this is paid by households. Drugs are typically the largest single item in household spending on health in poor countries, representing on average over half of the total.

In effect, limited public spending in poor countries means that the cost of financing medicines is privatised, with households picking up the bill. In sub-Saharan Africa almost two-thirds of total spending on pharmaceuticals is made by households, a figure which rises to over 80 per cent in South Asia (Figure 6).

**Figure 6: Pharmaceutical expenditures in selected regions and countries: private as a proportion of the total**



Source: World Health Organisation

Spending on medicines absorbs a large share of national and household health budgets. In countries such as Mali, Tanzania, Vietnam, and Colombia, pharmaceuticals account for over one-fifth of total public-health spending. However, this large slice of small budgets translates into derisory levels of spending on medicines per capita, ranging from 13–14 cents in countries like India and Mali, to 40–50 cents in Tanzania, and US\$3 in Colombia.

Chronic under-funding is not the only public-health problem facing poor countries. Others include poor public-health infrastructures, irrational drugs use, and distance from health facilities. But inadequate public investment is a major factor contributing to the vulnerability of poor households. It means that public-health systems provide little insulation against the risks and financial costs associated with illness. In Tanzania, it costs US\$3 to provide a single course of septrin, a front-line antibiotic used in the treatment of chest infections. In the event of resistance, the cost rises to US\$7 for more powerful antibiotics – equivalent to three times total per capita public-health spending. The discrepancy between public spending and the cost of treating even relatively minor sickness episodes helps to explain the large proportion of health expenditure that comes directly out of the pockets of households.

Across the developing world, the affordability of treatment is a function of household income and the cost of medicines. Poorer households are far more sensitive than richer households to price changes for the obvious reason that the same cost will represent a larger share of their income. For these households, spending on medicines may divert resources from other essential areas, such as food and education.



The problem can be illustrated by considering the treatment of pneumonia, a disease which claims over three million lives each year. In Zambia, it costs US\$8–10 to treat a single episode of the illness, provided that drugs are available. This is in a country where almost 60 per cent of the population survive on monthly incomes equivalent to less than US\$18 a month – an amount corresponding to the cost of a minimum food basket. In other words, families living on the very margins of existence would have to cut their food spending by one-half to treat a single case.

#### **The affordability of medicine**

Across the developing world, inability to afford drugs is one of the most powerful deterrents to poor people seeking formal health care – and it is at the heart of the linkage between poverty and illness. The costs of treatment are prohibitive even in countries with higher levels of average income. Doctors working in rural areas in the south of Egypt estimate the cost of treating a single pneumonia episode at more than ten per cent of the monthly income of an agricultural labourer.

Other common illnesses pose similarly extreme financial burdens on the poor. Each year, between 300 and 400 million people fall victim to malaria, resulting in over one million deaths. Most of these deaths are among African children. The cost of treating malaria ranges from around US\$1-2 for a course of chloroquine, which can be effective against non-resistant strains if used early enough, to US\$5 for a course of quinine. But research conducted by Oxfam in Uganda, in urban slums in the city of Kampala and in poor rural villages in the district of Luwero, consistently found that the poor were unable to pay these amounts. The consequences are often fatal. The following is an extract from a World Bank report describing a sickness episode in one family in northern Uganda:

'Difficulties started in March, when their five-year-old daughter, Grace, had a serious bout of malaria. Given the lack of money, their first recourse was with local herbs. Unfortunately, the little girl's condition did not improve. The family borrowed money and bought a few tablets of chloroquine and aspirin from the local shop. After some improvement, the girl's health sharply deteriorated two weeks later... Her parents then sold some chickens and, with the help of neighbours, took her to Ngoro Hospital, where she was immediately admitted. However, the family was asked to pay money they did not have. They went back home to try to look for money. It was too late. She died on 8 May and was buried the next day.'

As in countless other cases, the child's parents had delayed taking her to the health centre fearing that they would be unable to afford treatment. When they finally went to the clinic, they could not afford quinine – a more effective drug – and instead bought chloroquine and aspirin as a painkiller to relieve the symptoms. Even then they were able to afford less than half a full course.

Similar stories could be told across the developing world. Families are being confronted with agonising decisions, as their need to protect family health conflicts with their inability to afford treatment. Poor households face acute problems in purchasing drugs for the treatment of common diseases such as meningitis, sexually transmitted infections, and chest infections. In each case, inability to afford drugs translates into longer periods of illness and an increased burden on young girls and women, who bear the brunt of providing household care. In some cases, such as the one recounted above, the high price of medicines has tragic and fatal consequences. Crucially, it also means losses of income and productivity for families already living on the margins of existence.

The limited capacity of poor people to absorb the costs associated with sickness means that their demand for treatment is highly sensitive to price changes. In Burkina Faso the poorest one-fifth of the population were found to be four times more likely to stop treatment than their counterparts in the richest one-fifth when prices for drugs and treatment increased. Household-level research from a wide range of countries has highlighted a range of coping strategies which poor people use when faced with rising costs. These include:

- **Reduced consumption.** Evidence from Haiti shows that spending on medicine has left the poorest households unable to afford adequate diets for their children. Research in Uganda found that three-quarters of poor urban households reduced their spending on meals in the event of sickness episodes.
- **Distress sales.** Studies in Kenya have found that over one-quarter of land sales is the result of families attempting to raise cash to meet the cost of illness. In Vietnam, Oxfam research in rural areas found poor households selling buffalo to meet health costs. Such sales can have grave implications for future livelihoods and earnings capacity.
- **Household borrowing.** Household research carried out by Oxfam among urban slum dwellers in Manila found poor families borrowing from their extended family, and in extremis from money-lenders. Increased claims on kin and friends have also been documented in Zambia. Heavy reliance on support networks incurs costs.
- **Shifting spending.** One survey in Ghana cites the following comment by a poor farmer: 'The money spent on my wife's illness was earmarked for the payment of the children's school fees'. Spending on health is frequently

cited as a reason for withdrawing children from school – and where girls' education is less valued than that of boys, they are likely to be the first out.

- **Delaying or reducing health care.** Poor households are far more likely to delay seeking health care and purchasing medicines, or to opt for cheaper, less effective drugs. Health spending within the household is often rationed, frequently to the disadvantage of women.

Developing-country governments themselves could do far more to make medicines affordable to the poor. Many continue to spend far less on public health than on other priorities, such as military budgets. The impact of inadequate overall spending is compounded by inequitable patterns of spending. All too often, tertiary-level services used mainly by better-off groups absorb a disproportionately large part of the health budget, while primary health care is chronically underfunded. Spending constraints could be further reduced by international action to reduce the burden of debt servicing and increase aid.

Reform of the WTO's rules on patents cannot substitute for more equitable and efficient public-spending policies. But decisions taken at the WTO and by industrialised countries in this area will have a direct impact on poor households through their effects on the price and affordability of medicines. These effects need to be carefully considered to ensure that trade policies do not undermine national and international efforts to improve public health.



## 2 The WTO and drugs: the rules are loaded against the poor

**'Our combined strength enabled us to establish a global private sector-government network which laid the groundwork for what became TRIPS.'**

Edmund Pratt, Chief Executive Officer, Pfizer

**'Innovative drugs are increasingly unaffordable in developing countries, other than for a privileged elite. The ban on local copies will quite simply rule out access for the majority of the population.'**

Médecins Sans Frontières

Few of the victims of poverty-related diseases have heard of the WTO. Fewer still have had an opportunity to engage in debate over the implications of its rules for their welfare. Yet world trade rules have profound implications for developing countries – and nowhere more so than in the area of patents and public health. Governments in all developing regions are currently implementing sweeping changes in order to bring national legislation into line with WTO obligations. They are doing so in the face of threats of trade sanctions initiated by the US government acting on behalf of key corporations which stand to gain significant increases in their profits as a result of the new regime.

### The rules

The WTO's Agreement on Trade Related Intellectual Property Rights (TRIPS) is a dream come true for trade lawyers, and a nightmare for the general public. Its complexity and possible differences in interpretation mean that its implications for human development and poverty reduction are difficult to decipher. Another problem is that TRIPS is arguably the most heavily politicised area of WTO negotiations. Implementation will be governed as much by power politics and corporate lobbying as by legal texts.

The TRIPS framework covers seven parts and 73 articles of the trade agreement adopted at the end of the Uruguay Round of world trade talks in 1994. The framework establishes minimum standards in the field of patent protection which are derived from legislation in industrialised countries. All member states have to comply with these standards, where necessary by modifying their national legislation. In an important departure from previous conventions, pharmaceutical products are accorded full IP rights. In brief, the new regime:

- Creates a harmonised global system under which inventors are granted exclusive marketing rights for a minimum of 20 years for 'new and inventive' products. Enforcement of a country's compliance with TRIPS is ensured through the WTO dispute procedure, which places the burden of proof on the defendant. Countries failing to meet their obligations can be subjected to trade sanctions.
- Fully integrates sectors such as biotechnology and pharmaceuticals into the global regime. Prior to TRIPS, approximately 50 developing countries and several developed countries either excluded medicines from being patented, or provided patents only for production processes rather than products.

■ Gives developing countries until 2000, and Least Developed Countries (LDCs) until 2006, to bring their national legislation into line with WTO rules. Developing countries which did not have product patents have until 2005 to do the same. However, all countries are obliged to offer 'market exclusivity' (the equivalent of patent protection) to drugs for which patents were filed after 1995.

The TRIPS agreement explicitly acknowledges some of the tensions associated with patenting, including potential conflict between public and private interests. The preamble to the agreement states that IP rights should 'not themselves become barriers to legitimate trade'. Article 8 stipulates that, in framing national laws, members 'may ... adopt measures necessary to protect public health and nutrition, and to promote the public interest'. However, this principle is then qualified with the remarkable requirement that measures be 'consistent with' the Agreement. Oxfam believes that TRIPS should be amended to include a clear statement that 'nothing in the Agreement shall prevent the adoption of measures to protect public health'.

From a health-policy perspective, governments have two important policy instruments which help them to balance the public interest with the claims of patent holders. The first is the ability to override a patent by authorising a compulsory licence for production of a drug. TRIPS lays down conditions about how and when this can be done. The second is the right to engage in parallel importing, which means importing a patented drug from wherever it is sold cheapest, irrespective of the wishes of the patent-holder. Parallel importing is not covered by the TRIPS agreement, but the pharmaceutical TNCs and the US government are pressing for it to be banned in national patent legislation.

### **Compulsory licensing for production**

Governments are permitted to allow the exploitation of a patent without the owner's consent, provided this is justified by the general public interest. Under Article 31, compulsory licences can be granted to third parties on public-health grounds. French law, for example, explicitly allows for compulsory licences 'if required in the interests of public health', notably when drugs 'are made available to the public in insufficient quantity or quality or at abnormally high prices'. Compulsory licences can also be issued in response to national health emergencies. National legislation can provide special rules for compulsory licences granted to government agencies or contractors, notably by eliminating the patent holder's right to seek an injunction preventing the use of its patent (subject to adequate compensation). Compulsory licences can also be granted to restrain excessive prices.

The main limitation of a compulsory licence, in practice, is that a country needs to have a reasonably sophisticated pharmaceutical industry in order to produce the medicine concerned, and must be able to achieve economies of scale to bring the price down to affordable levels. The great majority of developing countries fail on both counts. The solution might be to import from a generic manufacturer in a larger country but this is unlikely to be economically viable unless a compulsory licence has also been issued in the exporting country. Even if it has, TRIPS allows compulsory licensing only if it is 'predominantly' for domestic needs, so the exporting country may find itself accused of breaking the rules.

The TRIPS agreement is drafted in a manner that will further limit the scope for state action. Authorisation for compulsory licensing can only be granted if the proposed user has made efforts to obtain a licence from the patent holder on



commercial terms, and if the patent holder is compensated. In addition, the scope and duration of compulsory licensing must be limited – and there are no clear criteria for determining the public-health grounds which may limit the rights of patent holders. While in theory the TRIPS agreement provides scope for combating monopoly pricing through national legislation, in practice this is likely to be easier in countries such as the USA, which has strong anti-trust laws and administrative capacity, than in developing countries. In each of these areas there is considerable potential for legal challenges from pharmaceutical companies, which are likely to prove most effective in countries which lack the capacity to meet them. The use or threat of trade sanctions in support of corporate claims will further weaken the position of developing-country governments.

#### **Parallel imports**

Where a patented product is marketed at a lower cost in another country, governments can allow 'parallel imports' from that country in order to take advantage of the price differential – but only if this option is built into their national legislation. The pharmaceutical TNCs are lobbying hard for developing countries to prohibit parallel importing. Paradoxically for a WTO agreement, TRIPS allows this prohibition, which is a barrier to international trade, thereby revealing a clear bias towards TNC interests.

Parallel importing can be used to circumvent differential pricing by companies, and is widely used. In the UK, parallel imports from within the European Union account for about 12 per cent of all prescriptions, reflecting the high prices charged by drugs companies in Britain compared with other European countries. Parallel imports account for almost one-fifth of sales of Glaxo Wellcome (GW) products in the UK.

But from a public-health perspective there are serious limitations with parallel importing as a safeguard mechanism. One is the absence of information on market prices for pharmaceutical products. Another is that pharmaceutical companies may seek to establish uniform global prices at the highest possible level. Unless governments retain the right to import generic-equivalent products, the protection against monopoly pricing is likely to prove weak.

#### **Early working and data protection**

In order to ensure that low-cost generic supplies can come on-stream immediately after patent expiry, TRIPS allows governments to include in national legislation the right of generic companies to develop, test, and register (though not stockpile) products prior to patent expiry. This is known as 'early working'. Developing countries have been under pressure from the USA not to allow early working in their patent laws. The US government and TNCs are also demanding protection for company data submitted to regulatory authorities on the testing and effectiveness of new drugs – a measure which will lead to further restriction of legitimate generic competition. The pharmaceutical TNCs claim that the data protection they seek is mandated by TRIPS, though this interpretation is contested by generic manufacturers.

#### **Price controls**

Governments retain the right to establish price controls, provided that they do not discriminate between foreign and local suppliers. However, price-control legislation is being fiercely resisted by drugs companies in both the developed and the developing world. Regrettably, TRIPS weakens the bargaining position of developing-country governments when dealing with companies, by making compulsory licensing a difficult last resort. Without the threat of compulsory licensing, a company is less likely to agree lower prices.



### **Implications for developing countries**

As indicated above, under the new rules, governments will no longer be permitted to allow local companies to produce, market, and export low-cost copies of patented drugs. This has major implications at two levels. First, in countries which have developed strong generic-drugs industries (which specialise in copying), there may be reduced self-reliance in pharmaceuticals, coupled with higher prices. Secondly, poor countries which lack strong generic industries will be prevented from importing from these sources.

One of the strongest generic-drugs industries is in India. Before 1970, the country was almost entirely dependent on imported drugs. Today, over 70 per cent of pharmaceuticals consumed in the country are locally produced. India has some 250 large pharmaceutical firms and 16,000 small producers. Local market prices are far lower than international prices for equivalent products. Moreover, India has one of the lowest inflation rates for drugs prices. Leading Indian companies such as Cipla and Ranbaxy are also important exporters. This transition has been achieved partly as a result of a 1970 patent law, under which local companies were allowed to copy patented drugs, provided that they found a new process. However, WTO rules commit India to full implementation of the new IP regime by 2005, and its patent law has already been reformed to give interim exclusive marketing rights for patents.

Egypt has also progressed rapidly towards self-reliance in pharmaceuticals. Today, over 90 per cent of drugs consumed are locally produced. Exports have also grown rapidly. As in India, local drug prices are far cheaper than those for imported equivalents, partly as a result of strict price controls. Local prices are on average one-fifth of those for imported equivalents. Like India, Egypt achieved these outcomes under a flexible IP law, according to which patents expired after ten

years – half of the period envisaged under the WTO regime. That law is now being reformed to ensure its compliance with WTO rules.

Other countries such as Brazil, Argentina, and Thailand have also developed strong local drugs industries under patent regimes which have placed a premium on improving access to essential drugs, rather than on the protection of monopoly rights. In each case, major legislative reforms have now been undertaken to bring domestic legislation into line with WTO rules, often under extreme duress. The US in particular has consistently used the threat of trade sanctions to ensure compliance with the TRIPS regime. In January 2001, the US government asked for a WTO dispute settlement panel to rule on aspects of Brazil's new patent legislation. This is the first time a formal complaint has been made about a developing country's alleged non-compliance with TRIPS, and is a clear declaration by Washington that the gloves are coming off at the WTO.

### **Undue corporate influence**

The WTO texts on IP are studiously analysed by armies of lawyers representing corporate interests and governments. Their economic implications are studied in depth with the help of sophisticated models developed by economists. But implementation of the rules will owe as much to power politics as to the letter of the law. The problem for poor countries is that public-health concerns are being side-lined because of the influence of pharmaceutical companies on the trade policies and practices of industrialised countries.

The introduction of IP rights to the WTO agenda was one of the core objectives of US trade policy during the Uruguay Round of world trade talks. Representatives of pharmaceutical companies occupied key positions on a special presidential trade advisory board created to develop policy.



Even before the trade agreement had been signed, the US Trade Representative (USTR) was using the threat of trade sanctions to demand stricter protection of US corporate interests in developing countries. In 1988, the 'Special 301' provision was adopted, granting the USTR the right to impose sanctions on countries with weak patent laws. It was promptly used against Brazil.

'Special 301' continues to serve as a corporate battering ram. Described by the ex-USTR, Charlene Barshefsky, as 'one of the most powerful weapons in our trade arsenal', it has been used to enforce compliance with WTO rules, and in some cases to go beyond them. The driving force behind the use of 'Special 301' for the enforcement of IP protection in drugs is the Pharmaceutical Research and Manufacturers of America (PhRMA). Its board includes representatives of corporate giants: Pfizer, GW, Novartis, Johnson and Johnson, Aventis, Merck, and Bayer. Its President, Alan Holmer, is himself a former USTR.

Members of PhRMA played a central role in persuading the Clinton Administration to threaten trade sanctions against South Africa when its government authorised the parallel import of cheap generic anti-HIV/AIDS drugs. It was also instrumental in persuading the US to protect the exclusive rights of Pfizer to market fluconazole in Thailand, where the government was planning to introduce a compulsory licensing arrangement. More recently, the Dominican Republic has faced the threat of US trade sanctions following complaints from members of PhRMA. The country's fast-growing textiles industry, which employs over 200,000 people, has been identified as a target because of its acute dependence on the American market.

More generally, PhRMA has maintained a sophisticated lobbying campaign directed against countries that it regards as a special

threat, notably India, Egypt, Argentina, and Brazil. One of the common features of these countries is that they have strong generic industries which not only provide low-cost competition in domestic markets, but also export low-cost generic drugs to third countries.

In January 2000 PhRMA filed petitions to the USTR claiming widespread and systematic non-compliance with world patent rules in these four countries. The use of price controls and compulsory licences to allow generic production of brand-name drugs was identified as a major problem, especially in India. Four months later, the USTR placed Brazil and Argentina on the 'Special 301' Priority Watch List – in effect, a short-list of candidates for unilateral trade sanctions. The annual 'Special 301' review also warned that future actions would be brought against other countries, including Israel, Egypt, and the Dominican Republic.

The number of countries threatened by 'Special 301' trade sanctions, which are themselves a violation of core WTO principles, is cause enough for concern. But the targeting of these threats has breached important safeguard principles which developing countries sought to establish in the TRIPS agreement. Countries have been selected on the grounds that they pose a strategic threat, either because of the size of their domestic market (as in Brazil), or because a particular generic industry has developed a major export capacity to supply third-country markets with low-cost drugs (e.g. India), or because it is a small country which has remained unresponsive to protracted threats (such as the Dominican Republic).

- India has been a consistently high-profile target for PhRMA, which regards the country's generic-drugs industry as a major threat to its members' interests. It claims market losses in excess of US\$100m in the Indian market and



further losses caused by generic companies which 'aggressively export their products to third countries.' India is one of the main sources of cheap drugs for Africa and other low-income countries. The Government of India has been warned that it faces trade sanctions if it continues to allow the generic copying of patented drugs and refuses to accept more restrictive criteria for issuing compulsory licences. Among the specific drugs targeted by PhRMA for more stringent patent protection is ciprofloxacin, one of the most widely used anti-infective drugs in the country. This action is taking place despite the fact that India is availing itself of the full transition period allowed for under WTO rules (i.e. until 2005), and that there are currently no serious grounds for initiating dispute settlements under WTO auspices. Despite this, an assessment by PhRMA in January 2001 concluded that 'PhRMA urges the USTR to initiate a dispute settlement in the WTO against the Government of India'.

- In the **Dominican Republic** the USTR has threatened to withdraw trade preferences following complaints from PhRMA. These include Generalised System of Preferences (GSP) arrangements for textiles and tobacco. At issue is a national industrial property bill which authorises compulsory licensing and parallel importing of cheap drugs. The wording of the PhRMA complaint against the Dominican Republic is instructive, in that it gives an insight into the broader strategy of attacking what are seen as strategic targets. 'The situation in the Dominican Republic poses a threat to regimes in neighbouring states, [and] is being used by activist organisations as a potential precedent to weaken the fabric of the TRIPS agreement.'

- **Argentina** has long been one of the prime targets of PhRMA, which describes the country

as 'the worst expropriator of US pharmaceuticals in the hemisphere', and a leader by bad example. Following a petition from PhRMA, a WTO dispute process was initiated against Argentina in May 2000. The aim of the action is to restrict recourse to compulsory licensing, to restrict the definition of national health emergencies, and to restrict the access of local generic producers to clinical test data on patented products (thereby delaying the introduction of generic competition). The PhRMA claims losses of over US\$50m annually in Argentina. **Brazil** was also included in the May 2000 dispute process because of alleged TRIPS violations in the compulsory licensing provisions in its patent law. Brazil is regarded as a major strategic priority since it is the biggest market in Latin America.

- In **Vietnam**, PhRMA has requested 'Special 301' action to counter what it describes as 'a pronounced trend towards protectionism in favour of locally-manufactured pharmaceutical products'. It has targeted key provisions in the new Vietnamese Civil Code which allow a compulsory licence to be issued if the government deems it necessary for the treatment or prevention of disease. PhRMA wants this provision withdrawn – and the USTR has threatened trade sanctions if action is not taken.

- In **Thailand**, the USTR has threatened trade sanctions unless the government dilutes laws allowing compulsory licensing and parallel importing, and withdraws drugs procurement policies which favour the local industry. These sanctions follow a PhRMA petition noting that Thailand is 'currently under severe pressure from non-government organisations' to issue compulsory licences for pharmaceutical products. PhRMA has also attacked the use



of parallel importing to gain access to low-cost copies of drugs categorised as 'essential' by the World Health Organisation (WHO). It claims that its members are losing sales in the order of US\$30m per annum as a result of patent violation.

It is not unreasonable for corporate interests to attempt to influence trade policies on IP. What is worrying in this case is the extent of that influence, and the absence of countervailing power. PhRMA is systematically targeting the very safeguard provisions which were negotiated to protect public health. The fact that they are able to do so reflects their formidable financial power and the close ties between government and industry. Between 1997 and 1999, PhRMA's members spent US\$236m lobbying Congress and the executive branch of government. Another US\$14m was provided to political parties in 1999 alone. Approximately two-thirds of corporate investment in political lobbying in the USA is directed towards the Republican Party.

The political pay-off to lobbying investments has been considerable. Many representations and appeals for trade sanctions from the pharmaceuticals industry have met with a sympathetic response from the USTR, resulting in extreme pressures on developing-country governments. In 1997 the South African government passed a law seeking to establish a market place for affordable medicine, by using both of the core safeguard provisions allowed by the WTO agreement (compulsory licensing and parallel importing). The aim was to reduce the cost of treating HIV/AIDS by between 50–90 per cent. With over four million AIDS sufferers, and national life-expectancy projected to fall by 20 years by 2010, it is difficult to argue that the government's action was not justified on public-health grounds. Yet it was subject to a legal challenge by a number

of pharmaceutical companies producing anti-retrovirals. The case is to be heard at the Constitutional Court in Pretoria in March 2001.

The same pattern of events has unfolded elsewhere. Whatever the letter of the WTO law, pharmaceutical companies have pressed for very restrictive policies on the use of compulsory licensing – and their demands have usually been supported by the USTR.

#### **Extending public-health safeguards**

Pharmaceutical products cannot be regarded as commodities in the same sense as cars, television sets, or electrical components. Vital public-health interests are at stake. This is why ring-fenced safeguards for public health should be seen as an integral part of the TRIPS agreement.

Developing countries themselves need to ensure that national legislation makes full use of the space, albeit limited, provided by existing safeguards. This means establishing in national legislation clear criteria for granting compulsory licences on public-health grounds. More generally, developing countries have to ensure that they develop the expertise and institutions needed to defend the public health of their citizens when disputes arise at the WTO. This means investing more resources in developing such capacity and, especially for the poorest countries, supporting national efforts through international assistance.

Ultimately, however, the WTO regime must be reformed to provide a more effective framework for protecting public-health interests. The burden of proof on governments seeking to introduce compulsory licences should be limited, with the onus placed squarely on patent holders to prove that public-health interests are not at stake. As argued below, there is also a strong case for limiting both the duration and the scope of patent protection provided under the WTO.

### 3 Patents and prices: the threat to public health

**'Patent rights are becoming ever more complicated and comprehensive, and the winners in the system of global ownership will be those with the resources to play the game. It is very difficult to see how the world's poorer countries will be among them: this flaw is fundamental and it carries real risks for the future.'**

Philippa Saunders, Essential Drugs Project, UK

**'Pharmaceutical companies have instigated a well-funded and well-organised campaign to block generics from entering the market place. And that is not good for competition.'**

Henry Menn, US Generic Pharmaceutical Industry

The WTO agreement signed in 1994 represented a decisive step towards a global trade system. Member states of the WTO must now abide by various multilateral agreements, including one on TRIPS.

The TRIPS agreement will have an impact on poor households and national health budgets through its effect on prices. The rules require countries to ensure market exclusivity for all products with patents filed after 1995. Since it will be illegal to produce low-cost generic copies for at least 20 years from the date of filing, the major source of downward pressure on prices will be removed.

The full impact of the new regime will not be felt immediately. While patent rules are already having adverse implications for the affordability of some vital drugs, such as those for HIV/AIDS, the TRIPS agreement is of less relevance to existing drugs than it is for new drugs in the pipeline. These drugs include products for the treatment of resistant forms of malaria, tuberculosis, pneumonia, gonorrhoea, meningitis, and shigella.

Some industrialised countries claim that the patenting issue is not crucial for public health in

developing countries since 'only' five per cent of the current WHO Model List of Essential Drugs is under patent. However, one criterion for inclusion in the list, which helps developing countries decide which medicines they must prioritise in the face of severe resource constraints, is price. This rules out a number of vital but expensive products, such as anti-HIV/AIDS drugs. With the spread of drug resistance and with new drugs appearing, the number of essential, patented products will grow. And as one developing-country trade official put it, 'When people's lives are at stake, five per cent is five per cent too many'. Some Third World governments argue that drugs on the WHO list or on comparable national lists should be exempted from patenting in developing countries.

#### **The costs of corporate monopoly**

Assessing the potential price effects of patents on pharmaceuticals is complicated, for a number of reasons. There is no uniformity in corporate pricing policy across different markets, making comparisons between prices for patented drugs and generic equivalents difficult. National legislation and the terms on which the WTO



agreement is implemented will also have an important bearing on price outcomes. Despite these provisions, there is compelling evidence that the new patenting rules will lead to significantly higher prices as competition from generic producers is restricted.

Price outcomes will inevitably vary across different markets. Broadly, the more competitive the local pharmaceutical market before the transition to a reinforced patent regime, the greater the likely effect on prices. Countries such as India, Brazil, Argentina, Egypt, and (when it joins the WTO) China can expect very large price increases. Similarly, countries in which past patent laws have allowed imports from these sources will experience major increases. For countries already providing stringent patent protection – including most OECD countries – price effects will be far more limited.

There are few reliable estimates of differences in the prices of medicines resulting from the introduction of patents. However, one simulation carried out for the Indian pharmaceutical market points to an average increase in price as a result of patenting of about 250 per cent. Other studies point to more modest increases.

Some idea of the order of magnitude of potential price shifts can be derived from past experience. Bayer introduced the patented anti-infective drug ciprofloxacin into India in the mid-1980s. Within seven years it was being produced and marketed by 48 local firms at a fraction of the initial import prices. Similarly, when GW marketed a version of zantac, a drug for the treatment of gastric ulcers, it was swiftly met by several competitors who were able to copy the drug. Patented brands of the two drugs were sold in the US and Europe at between 15 and 50 times the Indian generic price, depending on the market.

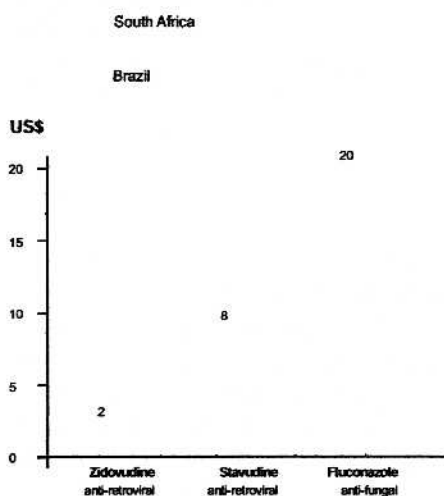
High-profile conflicts involving anti-HIV drugs have highlighted the cost-advantage enjoyed by generic

producers. The drug fluconazole, for example, which is used to treat HIV patients who have contracted meningitis, is marketed by generic companies in Thailand for US\$0.29 and in India for US\$0.64. This compares with market prices for brand-name drugs of US\$10.50 in Kenya, US\$27 in Guatemala, and (until recently) US\$8.25 in South Africa. In Thailand, Pfizer enjoyed exclusive marketing rights on the drug until these were withdrawn in 1999. The price then fell within a period of nine months to a little over three per cent of its previous level, as local generic competitors entered the market.

Figure 7 illustrates the difference in price between generic and non-generic products for anti-retroviral use in South Africa. In the case of zidovudine (AZT), which is used in the prevention of mother-to-child transmission, current generic prices in Brazil are less than half South African patent prices. Differentials of this size clearly have powerful implications for public-health provision.

Figure 7: Drug prices and patent costs

Prices for selected patented drugs in South Africa as a multiple of generic equivalents in Brazil



Source: MSF, HIV/AIDS medicines pricing report, London 2000

In Brazil, the government invoked 'national emergency' provisions in its patent law to start manufacturing low-cost copies of anti-retrovirals such as AZT. Today, a significant proportion of the 580,000 HIV-infected people in the country has access to treatment, with 60,000 receiving free treatment. The annual cost of triple-therapy treatment in Brazil is estimated at approximately US\$4,000 per annum, compared with over US\$15,000 in the USA. In Brazil's case, financing the similar levels of coverage with imported patented drugs would have cost the equivalent of the entire national drugs budget.

It is not just HIV/AIDS drugs that are marked by wide price differentials between patented and generic products. Price comparisons between India and Pakistan, where patent legislation has restricted the development of a generic-drugs industry, are instructive. Figure 8 compares prices for four patented drugs marketed in

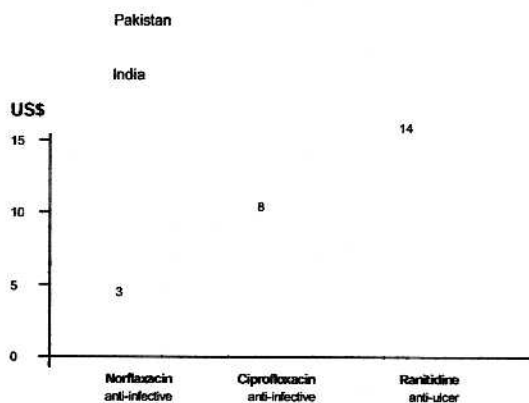
Pakistan with prices for their generic equivalents in India. It shows that price differentials range from 3 to 14 times in favour of the generic brand. For low-income populations, such differentials can determine whether or not they can afford vital medicines.

The presence of generic competition can exercise a powerful deflationary effect on prices for patented products. For instance in Peru, Bayer markets the drug Nifedipine at 32 times the price it charges in India, where it faces stiff local competition. Eroding this competition through reinforced patent protection will increase the scope for the generation of excessive profit margins, with attendant risks for public health. Evidence from China is instructive. It suggests that uncontrolled prices of protected drugs at small pharmacies in Beijing and Shanghai have risen by a factor of three to four times since the introduction of exclusive marketing rights in 1993.

Any price increase resulting from more stringent patent rules will have important implications for household expenditure and for public-health budgets. It is almost impossible to develop a credible estimate of these overall costs, partly because there will be wide variations associated with differences in national legislation, and partly because investment and supply responses are difficult to predict. Such estimates as there are often reflect calculations by industry of losses incurred as a result of weak patent protection. For what they are worth, they suggest cause for serious concern. Exercises carried out by PhRMA put these losses at over US\$1.5bn for Argentina, Brazil, and India alone. Another estimate puts the global gain to the pharmaceutical industry from reinforced patent protection at over US\$3bn. The gains for US corporate interests will mean a significant foreign exchange loss for developing countries. They will

**Figure 8: Drug prices and patent costs**

Prices for selected patented drugs in Pakistan as a multiple of generic equivalents in India



Source: The Introduction of pharmaceutical product patents in India  
Lanjouw, J. National Bureau of Economic Research, 1997



also lead to acute budgetary pressures, as governments attempt to absorb higher-cost structures into their national drugs budgets.

One of the reasons why it is hard to compare prices between generic and brand-name products is the lack of transparency and consistency in the pricing policies of pharmaceutical companies. Pharmaceutical pricing is more of an art than a science. Companies charge different prices for drugs across countries, dependent on, among other factors, estimates of what the market will bear. The principle is relatively simple: companies charge what they can get away with, while people and governments pay what they can afford.

This conclusion was borne out by a recent UNAIDS–UNICEF–WHO comparison of international prices for patented drugs used in the treatment of HIV/AIDS-related conditions. Prices for zidovudine varied by a factor of two, for fluconazole by a factor of three, and for ciprofloxacin by a factor of 45. These variations apply across industrialised as well as developing countries. For instance, prices for HIV/AIDS-related drugs in Britain are consistently two to three times higher than in Spain.

Price variations between developed and developing countries are especially marked, though not in the pattern of lower prices for lower-income countries which might be expected. For instance, lamivudine is marketed by GW in Africa at prices 20 per cent higher on average than in industrialised countries. Prices for branded versions of the product are higher in Mozambique, where over half of the population lives below the poverty line and 14 per cent of the population has the HIV virus, than in the USA. There are also very large price variations between Mozambique (US\$810) and Malawi (US\$530), suggesting a significant discrepancy

between corporate pricing strategy and public-health needs. Generic-equivalent products are available in India at prices (around US\$118) that are far lower than the brand-name price charged in Africa.

These price variations are important. They point towards the detrimental effect of monopoly power, coupled with a failure to adopt socially responsible pricing policies. The fact that only limited price comparison data are available compounds the problem. Companies do not publish prices charged across different markets, usually on the grounds of commercial sensitivity. This is why Brazil and Zimbabwe proposed in May 2000 that the WHO start an international database of drugs prices. Such a database could highlight major price discrepancies for drugs vital to public health, thereby enabling governments to make informed decisions as to whether parallel imports and compulsory licensing are justified. However, the proposal has been fiercely resisted by the USA and the major pharmaceutical companies.

#### **Pipeline threats: implications for treatment of drug-resistant diseases**

Most of the drugs that will come on stream as the new WTO rules are implemented have been developed with a view to patenting and marketing in rich countries. This has created unwarranted complacency about the implications of TRIPS for developing countries. In reality, many of the new anti-bacterial drugs now being developed could bring enormous benefits to poorer countries, provided that they are delivered on affordable terms. This is especially true with respect to the treatment of drug-resistant strains.

Drug-resistance poses an enormous threat to poor communities across the developing world. It means that illness is less susceptible to treatment, and that the costs of treatment increase – in some

cases dramatically. The danger is that, in the absence of competition from generic-drugs producers, new patented drugs will be placed far beyond the means of the poor. Examples of drug resistance include:

• **Pneumonia (3.5 million deaths annually).**

Formerly effective front-line medications used to combat pneumonia and other respiratory tract infections now fail in the treatment of over 70 per cent of chest infections, according to a WHO study. Trials for several drugs potentially effective against resistant forms of pneumonia are now in an advanced stage. These drugs, which will be patented, include faropenem (Bayer) and levaquine (RW Johnson). One of the most promising drugs in this area is Ketek, the first in a new generation of antibiotics which is proving highly effective against pneumonia and influenza. Aventis is expected to launch the patented version of the drug in 2001.

Restrictions on the development of generic versions will place it beyond the means of most sufferers in poor countries.

• **Diarrhoea (2.2 million deaths annually).**

Shigella is a highly virulent microbe responsible for half of all episodes of bloody diarrhoea in young children. It is directly responsible for an estimated 375,000 child deaths. In the past, many deaths from diarrhoea could be easily controlled with cheap generic drugs such as co-trimoxazole or ampicillin. However, resistance to these drugs is now very common (in over three-quarters of all cases in Tanzania, for example).

Ciprofloxacin is one of the most effective of these drugs. The patented version is marketed by Bayer in Pakistan and in South Africa (where the patent has been filed) at prices respectively eight and twelve times higher than the generic version in India. Restrictions on the availability

of generic ciprofloxacin resulting from more stringent patent rules would have grave public-health consequences. Several drugs relevant to the treatment of diarrhoea are now on trial.

• **Malaria (1.1 million deaths annually).**

Resistance to the lowest-cost front-line treatment, chloroquine, is now widespread in over 70 countries where the disease is a major killer, and resistance to sulfadoxine/pyrimethamine is growing. GSK's Malarone has proved 98 per cent effective in the treatment of drug-resistant malaria. However, it is too expensive for most patients. Competition from generic producers is not permitted due to its patented status.

• **Gonorrhoea (62 million new cases annually).** The development of anti-microbial resistance in gonorrhoea has been described by the WHO as 'one of the major health care disasters of the 20th Century'. It has made gonorrhoea a driving force in the HIV/AIDS epidemic. Effective treatment is available in the form of ciprofloxacin and ceftriaxone (patented by Roche). However, the costs of effective treatment are relatively high. As with all sexually transmitted infection, women are particularly susceptible, with untreated gonorrhoea greatly enhancing the risk of HIV/AIDS infection, infertility, and miscarriages.

There are other examples of the potential costs which may be associated with patenting. Drugs on trial for the treatment of hepatitis (such as Entecavir, produced by Bristol-Myers Squibb) and viral meningitis, along with other anti-infective drugs and vaccines, offer potential benefits for developing countries, even though they have been developed with the US market in mind. But these benefits will be lost if prices in developing countries reflect the application of strict patent protection.



The pharmaceutical industry itself acknowledges that the affordability of medicines in developing countries with poor populations poses a serious public-health problem. It has responded by developing, in co-operation with the United Nations (UN) and Northern governments, a range of initiatives which aim to increase the supply of drugs and reduce their costs. There is now a wide range of these international initiatives. Under the umbrella of the 'Accelerating Access to HIV/AIDS Care and Treatment Initiative', five companies (GW, Merck, Bristol-Myers Squibb, Hoffman-LaRoche, and Boehringer Ingelheim) have agreed to provide anti-HIV/AIDS drugs at prices 15–20 per cent of those prevailing in the USA. The Global Alliance for Vaccine and Immunisation (GAVI), established with a US\$750m grant from the Gates Foundation, administered by UNICEF and the WHO and supported by industry, is targeting the 30 million children born each year who are not fully immunised. Similarly broad partnerships lie behind the WHO's Roll-Back Malaria Initiative and a parallel effort to end tuberculosis. Pharmaceutical companies have played an important role in providing drugs, either on heavily subsidised terms or as donations. And there have been major advances. For example, the Merck Corporation is committed to providing free drugs for the treatment of river blindness until the disease is eliminated.

Each of these initiatives has played an important part in advancing public-health interests. Yet there are serious problems with this broad approach. While the Accelerating Access Initiative may be providing a significant price discount, this remains insufficient to broaden access on anything like the scale required. In the case of 'Roll-Back Malaria', the drug Malarone could be the catalyst for a major breakthrough, given that it is effective against 98 per cent of even the most virulent

strains. However, it is expensive: one course of treatment costs approximately US\$42. To its credit, GW pledged in 1996 to donate one million doses, each year, but this falls far short of the quantity required for an illness that affects 300 million people annually. Actual donations have been measured in hundreds, rather than millions, of doses in part due to the programme's attempts to ensure Malarone is only used on those cases resistant to other treatments. More broadly, corporate philanthropy is often less benign than it appears. There are frequently restrictions on the quantities of drugs that will be supplied, and even where prices are reduced, they sometimes remain higher than those for generic products.

Yet the benefits of public-private partnerships are being eroded by TRIPS rules which place commercial profit before human development. The case of HIV/AIDS is instructive. While companies are offering subsidised drugs, in the sense that there is a significant discount against US market prices, the Accelerating Access Initiative does not involve the generic producers, even though they could have offered the medicines at lower concessionary rates than those for branded products. The Government of Kenya has publicly criticised pharmaceutical companies for donating drugs with one hand, and then preventing the country from producing lower-cost variants with the other. In Zambia, the cost of donated AZT, financed by UN agencies and donors, is higher than the cost of generic products available from India and Thailand. This suggests that the benefits of publicly financed spending, including the numbers of patients treated, are being restricted. In other words, the public-health gains associated with public-private partnerships are being eroded by what amounts to corporate misuse of monopoly power.

## 4 **The case for reform: beyond corporate philanthropy**

**'Weakening intellectual property rights will ... serve to reduce the incentives for research into the new medicines of the future, including innovation for neglected issues.'**

Glaxo Wellcome Annual Report, 2000

**'I know TRIPS will be a disaster in India. We are not against patents but we are against monopolies. In a country with a population of 1 billion people we cannot afford monopolies.'**

Dr Y.K. Hamied, CIPLA, India

**'If the . . . drugs companies . . . really means [sic] business, they should waive their patent rights and let developing countries make the drugs themselves under their supervision. Kenya already has the capacity to make most of these drugs. It is the big five who are stopping us.'**

Dr Mohammed Abdullah, Kenya Aids Control Council

The strengthening of IP rights through the WTO has raised far wider development issues. In an increasingly knowledge-based global economy, access to new technologies is vital. Yet patent rules threaten to drive up the cost of technology transfer, widening another of the divides separating rich from poor countries: namely, the knowledge divide. In the specific case of pharmaceutical products, they threaten to deprive poor people of access to products vital to their well-being. The problem is that IP provisions have moved beyond their proper function of providing reasonable rewards to inventors, to create long-term, tighter monopolies in developing countries.

Patents are essentially a contract between society and inventors drawn up and enforced by governments in order to encourage innovation. The rationale is simple. If creators of knowledge do not get a reward for their inventions because

they can be freely copied by others, they will not invest in producing new ideas which could benefit the public. Patents provide a reward in the form of exclusive marketing rights. In the words of Abraham Lincoln, they add 'the fuel of interest to the fire of ideas'. But IP rights can sometimes undermine access to products which are essential for the public good, including vital medicines.

Straightforward as the idea may be, the history of patents has been dogged by controversy. In seventeenth-century Europe they were used by absolutist monarchs to reward royal favourites and create private monopolies at great cost to the public. More generally, while the principle of exclusive marketing rights is widely accepted, there is less agreement on the duration and scope of patent protection.

Arguments concerning duration and scope have figured prominently in the debate on patents for



pharmaceutical products. Pharmaceutical companies point to the high cost of developing new drugs as a justification for strong patent protection. They also argue that such protection is vital to stimulate the R&D needed to combat poverty-related diseases in developing countries (see the GW quote above).

There is no doubt that patents are highly profitable, and that they have an important bearing on the share prices of pharmaceutical corporations. But the arguments for extending patent protection and providing stricter enforcement through the WTO, particularly in developing countries, are at best weak, and at worst specious.

Take the issue of finance for R&D. What matters here is not the fact that drugs are costly to develop, but the rate of return to investment – and the pharmaceutical industry already achieved some of the highest profit margins in the corporate world before the new TRIPS regime. For example, GW achieved an operating profit of 31 per cent in 1999. Operating profit in the industry as a whole is typically in the range of 20–23 per cent, which suggests that ‘weak’ patent regimes in developing countries have not, thus far, had an adverse effect on profitability. The fact that pharmaceutical corporations typically spend more than twice as much on marketing as they do on R&D raises questions about how much of the revenue from patents actually finds its way into socially beneficial research. Industry also tends to gloss over the existence of public funding for the development of products patented by industry. Taxpayers and publicly funded institutions often play a key role in discovering new inventions, with the pharmaceutical industry obtaining the patent – and reaping the financial rewards – after the basic discovery. These institutions are now becoming more reluctant to unconditionally hand over their

research. In December 2000 a dispute between the US National Institutes of Health (NIH) and Bristol-Myers Squibb became public. NIH is demanding US\$9.1m in royalties from overseas sales of didanosine, used in the treatment of HIV/AIDS.

Another problem, and constant source of complaint from the generic-drugs industry, is that pharmaceutical companies creatively use the patent system to extend monopolies and boost profits. In 1999 SmithKline Beecham (SB) secured a new patent on its 20-year-old best-selling drug, Augmentin, by modifying the paediatric version. Although the old forms will be available off-patent, extensive marketing is likely to induce doctors to prescribe the new drug when it comes on the market. Other high-profile cases have included Eli Lilly seeking extensions of its patent on Prozac (an anti-depressant with sales in excess of US\$2bn annually), and the US Federal Trade Commission prosecuting Aventis for paying generic manufacturers not to produce low-cost rivals to its brand-name drugs. A large number of the drugs that have qualified for an extension in patent protection have not been subjected to major innovations with regard to their active ingredients.

It is not difficult to see why pharmaceutical corporations seek to extend the period of patent protection. When a US court decided in August 2000 to grant Eli Lilly two years less extension to its patent on Prozac than the company had been requesting, its share value fell by almost one-third, wiping US\$38bn from its market capitalisation. Patent expiry, and the prospect of competition from generic versions of drugs marketed at a fraction of the brand-name price, pose obvious problems for corporations precisely because share price valuation is increasingly determined by the patent life of key drugs. In effect, the



markets are rewarding monopoly. But the costs of monopoly pricing are borne by households and public-health budgets. That is why patent extension is a source of serious concern to health-service managers in the industrialised world, where spiralling drugs prices are a source of growing budgetary pressure. In developing countries, where budgets are far more limited, the consequences can be devastating.

There are other factors which weaken the economic case for reinforced patent protection. Lengthy patent periods can have the effect of restricting innovation and creating what amount to monopoly rents for patent holders. While these rents can create gains for some, they imply costs for others. Claims to IP are concentrated among very few countries. Industrialised countries account for over 97 per cent of patents world-wide – and around half of royalty payments for patents are directed towards the USA. This has an obvious relevance in drugs markets, where there is a strong public interest in competition in order to lower prices. There are also important equity issues at stake. It is estimated that around one-quarter of the compounds used in the manufacture of patented drugs are derived from plants in developing countries, many of which have been used for medicinal purposes for generations. Yet the royalty payments associated with these compounds accrue to Northern corporations.

### **Closing the R&D gap**

What of the claim that increased patent protection will help to close the health divide by creating incentives to invest in the discovery of cures for poverty-related illness? If it were true, it would amount to a compelling case for patents. Unfortunately, it is not. The reason that such little investment is directed towards poor countries is economic: poverty restricts the size of markets,

and hence the potential for generating profit. Sub-Saharan Africa may account for over 40 per cent of the global burden of disease, and its people face a higher risk of premature death than their counterparts in any other region. Yet it accounts for only 0.1 per cent of the R&D spending of major drugs pharmaceuticals.

Less than 10 per cent of the US\$60bn spent on R&D on pharmaceutical products each year is directed towards diseases of the poor. Of the 1,233 new drugs that reached the market between 1975 and 1997, only 13 were approved specifically to treat tropical diseases (including several drugs developed by the US army to treat soldiers serving in tropical areas and others developed for veterinary medicine).

Over 95 per cent of HIV/AIDS cases are in the developing world. But research is concentrated in rich countries, where governments are responding to the epidemic through high-cost drug treatments which are far beyond the reach of the poorest countries. Vaccine research is chronically under-funded and directed largely towards illnesses of concern to populations in wealthy countries. Many health experts believe that tuberculosis, which claims more than two million lives each year, and malaria would probably both be susceptible to a vaccine. Yet there is little research in this area – and there are no new drugs and vaccines relevant to poverty-related communicable disease in the pipeline.

The reason for the discrepancy between spending on R&D and the global distribution of illness is relatively straightforward. Like other private investors, large drugs companies gear their research towards markets that are likely to generate the largest profit. The problem in developing countries is that low average incomes and widespread poverty restrict the potential



returns from research. The most profitable medicines are those for treating chronic, long-term ailments of the rich world, such as high-cholesterol, depression and ulcers.

Poor countries scarcely register as a source of profit on the balance sheets of major drugs companies. In the last analysis, this explains why such a small share of the research budget aimed at finding an HIV/AIDS vaccine is directed towards virus sub-types prevalent in poor countries. It also explains the derisory level of funding directed towards tuberculosis, malaria, and sleeping sickness. Strengthening patents will not change this picture.

Nor will it create incentives for R&D in developing countries – another widely voiced claim. The vast majority of developing countries lack the capacity to enter the R&D market on any scale. Sixty developing countries have no pharmaceutical industry at all. Another 87 simply assemble finished products from imported ingredients. Only five have innovative capabilities, and none of these has significant research into new molecules. For instance, India's entire generic industry spends just US\$50m annually on research, which is less than one-tenth of what the pharmaceutical transnational companies claim it costs to bring a single drug on to the market. India's research effort can be put into context by comparing it with the US\$4bn research budget spent by each of the world's two largest drugs companies, GSK and Pfizer. In the global competition to capture the benefits of the WTO patent regime, the scales are heavily weighted in favour of rich countries and powerful corporations.

What is required is a major international initiative aimed at financing the R&D needed to enhance the health of the poor, without an eye to corporate profit margins. Such an initiative will have to be led by governments, with private foundations and industry playing a strong but

supportive role. The claim that only the private sector is capable of filling the current vacuum is flawed. The Green Revolution in agriculture was the product of research by public institutes in developing countries, supported by Northern governments and private foundations. The research linked publicly funded research institutes – such as the International Rice Research Institute in the Philippines – and helped to advance knowledge geared towards raising agricultural productivity and improving food security.

More recently, the Human Genome Project (HGP) – a collaborative effort involving publicly and privately funded research institutes in the USA, Britain, France, Germany, and Japan, and foundations such as the Wellcome Trust – has achieved dramatic advances in the world's understanding of DNA. The HGP, an international collaborative venture spanning five major centres and laboratories worldwide, has a powerful resonance in the field of pharmaceutical patenting. One of its core principles is that the results of this research are placed in the public domain, allowing researchers worldwide to improve collective understanding of genomes. What is needed, on a far larger scale, is a similar research effort to address the health problems facing the world's poor, with governments leading initiatives to direct investment into the large gaps left by market-oriented R&D. Northern governments will inevitably have to play the leading role in mobilising resources, though all governments have a part to play, both in generating finance and in developing research capacity at a national and regional level.



## Recommendations

The potential benefits of international co-operation to control infectious diseases are enormous. For the poor communities currently bearing the brunt of the global disease burden, the benefits are self-evident. Apart from reducing suffering, improved health is a pre-condition for achieving more sustainable livelihoods and greater prosperity. But the benefits extend beyond households. Reducing avoidable death, enhancing prospects for child survival, and improving the quality of life for the poor is a moral imperative for all people. It is also a matter of shared interests. Infectious diseases do not respect national borders, and none of us is immune to the consequences of the poverty associated with widespread sickness.

Reform of world trade rules on pharmaceuticals matters for a simple reason: they are unjust. Modelled on the laws of rich countries, most of which refused to countenance them until they had reached a high level of economic development, they are entirely inappropriate for poor countries. The rigid application of strengthened patent rules threatens to place vital medicines beyond the means of millions of people. The influence of private corporate interests in the design and enforcement of WTO rules raises further questions. It casts a shadow over a multilateral system which is facing a deepening crisis of legitimacy, in part because of its failure to address the great challenges posed by global poverty and inequality. The crude assertion of corporate power and narrowly defined national self-interest over the wider public interest in reducing the international health divide can only deepen that crisis.

The case for reform is straightforward. Each week, over 200,000 people die from infectious diseases – many of them because they cannot afford basic medicines. As currently constructed, world trade rules will increase the price of drugs. They will do so by preventing countries from developing low-cost medicines accessible to low-income populations. In short, the rules are placing corporate profit above human need.

Public pressure and political challenges mounted by governments in developing countries are starting to influence the debate on the application of patent rules to pharmaceutical products. The

British Government, in its recent White Paper on Globalisation, announced that it would establish a commission to look at how IP rules could be reformed to better protect the interests of the poor. This is an encouraging step in the right direction. But research and reflection is no substitute for substantive action in the following areas.

### **1. Change trade rules to cut the cost of vital medicines.**

Developing countries should retain the right to produce, market, import, and export affordable medicines. The principles of patent protection set out in the WTO agreement should not be used in ways which inhibit this right. Provisions in the TRIPS agreement to safeguard public health through compulsory licensing and parallel importing should be strengthened, and the scope for legal challenges by patent holders limited. Under no circumstances should bilateral and regional economic agreements be used to ratchet up patent protection. The duration of patent protection on pharmaceutical products should be shortened and the scope of protection limited.

Consistent with international human rights obligations, it should be agreed that the health crisis in many poor countries constitutes a national emergency. Under Article 31, WTO members may waive the requirement to seek voluntary licences in cases of such emergencies or other extreme circumstances. This would allow governments to address local health needs without going through arduous and prolonged negotiations on patents.



**2. End rich-country bullying in negotiations on patents.**

The WTO should prevent industrialised countries from demanding high levels of patent protection in developing countries through the threat or use of unilateral trade sanctions or legal challenges. Section 301 of US trade legislation should be repealed with immediate effect.

**3. Invest in a research fund for diseases of the poor.**

Given the lack of commercial interest in researching infectious diseases in developing countries, a US\$5bn international fund should be set up under the auspices of the WHO to support a global network of public research institutions dedicated to developing new medicines and vaccines. Public investment and international co-operation, rather than extended patent rights, hold the key to narrowing the global health divide.

**4. Pharmaceutical giants should cut the cost of key medicines to developing countries.**

Pharmaceutical companies should reduce the price of key medicines in developing countries so that they are affordable to the poor. Prices should be determined as part of an international and transparent system of equitable pricing, developed in conjunction with the WHO, with price differentials based on the Human Development Index and on a country's ability to pay. As the world's largest pharmaceutical company, GSK should lead by good example, making the drug Malarone available to developing countries at a price no higher than existing malaria treatments.

**5. Pharmaceutical giants should balance public health and their patent claims in poor countries.**

Pharmaceutical companies should exercise social responsibility with respect to their patent

claims. They should not seek to enforce patent claims in the poorest countries on drugs essential to public health.

**6. Assess the impact of stronger patents on the health of poor people.**

The forthcoming review of TRIPS should include a comprehensive assessment of its effects on the affordability and availability of medicines in developing countries. The review should be supported by independent studies by the WHO and other relevant international organisations, in consultation with governments and public-interest groups.

**7. Stop patent protection on bio-piracy.**

WTO rules should be amended to prevent bio-piracy. As a first step, the TRIPS regime should be harmonised with the Convention on Biodiversity, with patent holders required to disclose the origin of biological materials and to demonstrate prior informed consent of the original holders of knowledge applied in the development of patented products.

**8. An international fund should be established to subsidise drug purchases and delivery systems in the poorest countries.**

An international fund for medicines will offer long-term support and will remove the arbitrariness and uncertainty of bilateral drug donations by companies. It could also reduce costs by organising international tenders for bulk purchase. Aid funds are also required to support the all-important delivery systems, which must be properly integrated into national health services. The decline in aid for health services in developing countries should be reversed.

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## Further reading

For a good overview of intellectual property rights see Maskus, Keith (2000), *Intellectual Property Rights in the Global Economy*, Washington, Institute for International Economics; The Economist (2000), 'Who owns the knowledge economy?' April 81-4 2000: 95-95. London.

On the health profile of poor countries and the global distribution of disease see: Gwatkin, Davidson and Guillot, Michel (2000), *The Burden of Disease Among the Global Poor*, Human Development Network, World Bank, Washington; World Health Organisation, *The World Health Report 1999*, Geneva. See also WHO (2000), *Overcoming Antimicrobial Resistance: Report on Infectious Diseases*, Geneva.

While the price of medicine is only one of the factors influencing access to health care, it is an important one. On the problems faced by poor people in meeting health costs and their various coping strategies see: Russell, Steven (1996), 'Ability to pay for health care: concepts and evidence', *Health Policy and Planning* 11/3:219-237, Oxford University Press, Oxford; Gilson, Lucy (1988), *Government Health care Charges: Is Equity Being Abandoned?* Evaluation and Planning Centre for Health, London School of Hygiene and Tropical Medicine, London; Chamber, Robert (1982), 'Health, agriculture and rural poverty: why seasons matter', *Journal of Development Studies* 18:217-238. Sage, London.

On the extent of payments for medicines made by households in developing countries see Filmer, Deon, Hammer, Jeffrey and Pritchett Lant (1997), *Health Policy in Poor Countries: Weak Links in the Chain*, World Bank, Washington, 1997.

On access to essential drugs see Scholtz, Michael (1999), 'International trade and public health', mimeo, paper presented at WHO Conference on Increasing Access to Essential Drugs, WHO, Amsterdam, 1999. See also Reich, Michael (2000), 'The global drugs gap', *Science* 287:1979-1981.

The price of medicines has important implications for public health budgets, and for the capacity of governments to improve access to treatment. On this see WHO, *Health Reform and Drugs Financing: Selected Topics*, Action Programme on Essential Drugs, WHO, Geneva.

There are serious methodological problems involved in considering the implications of strengthened patent systems for prices of medicines. However, there are a number of studies that look at this issue, either by using economic modelling, or by comparing prices of patented drugs with generic drugs. The following are among the most important. See Watal, Jayashree (2000), *Access to Essential Medicines in Developing Countries: Does the WTO TRIPS Agreement Hinder It?* Science, Technology and Innovation Discussion Paper 8, Centre for International Development, Harvard University, Cambridge (MA); Lanjouw, Jean (1998), *The Introduction of Pharmaceutical Product patents in India: Heartless Exploitation of the Poor and Suffering?* National Bureau of Economic Research, Cambridge (MA); El-Shinnawy, Azza (1999), *The Impact of Strengthening Intellectual property Protection in Egypt on the Pharmaceutical Industry: a Preliminary Assessment*, mimeo, Development Studies Institute, London School of Economics, London. Bala, K and Sagoo, K (1999), *Patents and Prices*, mimeo, Health Action International and Consumers International, Amsterdam.

Médecins Sans Frontières (MSF) monitors differences in prices for patented and generic versions of anti-HIV/AIDS drugs. See MSF (2000) 'Access to Essential Medicines', MSF, London (available from <http://msf.org/advocacy>). For a recent review of price differentials for HIV/AIDS drugs see UNAIDS/UNICEF/WHO (2000), *Essential drugs used in the care of people living with HIV: sources and prices*, UNAIDS, Geneva. See also Health Action International website (<http://www.haiweb.org>).

For a good description of the Trade Related Intellectual Property Rights (TRIPS) agreement in the WTO and the scope for public health safeguards see World Health Organisation (1997), *Globalisation and Access to Drugs: Perspectives on the WTO/TRIPS Agreement*, Health Economics and Drugs DAP Series 7, Geneva. On the implications of TRIPS for public health see South Centre (2000), *Integrating Public Health Concerns into Patent Legislation in Developing Countries*, South Centre, Geneva. For a critical evaluation see Correa, Carlos (1997), *Intellectual Property rights: the WTO and Developing Countries*, Zed Books, London. Third World Economics (1999), *Trying Times Ahead in TRIPS Implementation*, 16-30 September, 1999, Malaysia.

On the activities of the Pharmaceutical Research and Manufacturers of America, including their advocacy in favour of trade sanctions against developing countries, the PhRMA web site provides a one-stop source of information (<http://www.phrma.org>). On the role of the United States Trade Representatives Office in threatening trade sanctions over patent disputes see the 'Special 301' reports on <http://www.ustro.org/301>.

**To get involved with Oxfam's Cut the Cost campaign:  
phone 01865 312610 or [www.oxfam.org.uk/cutthecost](http://www.oxfam.org.uk/cutthecost)**



## JOINT PRESS RELEASE OF MEDECINS SANS FRONTIERES (MSF), TREATMENT ACTION CAMPAIGN (TAC) AND OXFAM

Oxfam news releases - 2002/01/29

### Generic AIDS Drugs Offer New Lease on Life to South Africans

Importation of generics cuts price in half

29 January 2002, Johannesburg ? Yesterday, three members of the Treatment Action Campaign, (TAC) returned to South Africa from Brazil carrying generic drugs manufactured for use in an AIDS treatment program in Khayelitsha. At a press conference today, TAC and MSF explained that the drugs carried from Brazil were the second shipment of Brazilian drugs and that as of today more than 50 people are already taking the Brazilian medicines in Khayelitsha.

To guarantee the quality of these drugs, an authorisation from the Medicines Control Council (MCC), the South African drug regulatory authority, was obtained prior to their use.

"Last week in Brazil we saw what happens when a government decides to tackle HIV/AIDS. The Brazilians' decision to offer universal access to antiretroviral therapy even in the poorest areas of the country is keeping tens of thousands of people alive," said Zackie Achmat of the Treatment Action Campaign. "Central to the success of Brazil's AIDS programme is their willingness to do anything necessary to source the lowest cost quality ARVS. The South African government should pursue compulsory licensing to ensure that generic antiretrovirals can be produced and/or imported in South Africa."

At a press conference today, the NGOs said that the court victory of the South African government against multinational pharmaceutical companies had opened the door to improved access to affordable medicines. "The South African government may need international financial help to provide treatment, but these needs will be dramatically reduced if the government takes steps to use the most affordable drugs available on the worldwide market, as the multinational pharmaceutical companies are still charging high prices for these drugs," said Dan Mullins of Oxfam.

Despite the national government's refusal to provide antiretroviral treatment, three clinics run by Medecins Sans Frontieres (MSF) within the government primary health care centres offer a comprehensive package of services to people living with HIV/AIDS, including antiretroviral therapy. This project is part of an agreement between MSF and the government of the Western Cape, signed two years ago with the express intent to test the feasibility of generic antiretroviral therapy. These clinics, located in Khayelitsha, a sprawling township of 500,000 people outside Cape Town, were opened in April 2000 and have provided treatment for opportunistic infections for over 2,300 people living with HIV/AIDS.

In May 2001, combination antiretroviral therapy was introduced for a group of people in advanced stages of AIDS. To date, 85 people have received antiretroviral therapy and 50 of these are receiving Brazilian medicines. Using generic antiretrovirals offers the possibility of treating twice the number of people with the same amount of money.

"I have personally benefited from the MSF antiretroviral programme, and I have gone to Brazil to bring back generics so that more people like me can have access to these medicines," said Matthew Damane, a person living with AIDS who is receiving antiretroviral therapy as part of the MSF programme in Khayelitsha. "The government should publicly accept the effectiveness of these medicines and make them available to people with AIDS in South Africa."

"Our project shows that antiretroviral therapy is feasible in a resource-poor setting, contrary to those who insist that poor Africans are not able to successfully take these drugs. Patients who were critically ill are now returning to their normal lives," said Dr. Eric Goemaere of MSF South Africa. "We have seen firsthand that these drugs can be used safely and effectively here in South Africa. As medical professionals, it is our duty to offer these benefits to as many patients as possible."

Similar initiatives are springing up elsewhere around the country as medical staff become increasingly frustrated by the lack of action from the national government. Nonetheless, the price of medicines continues to be a critical problem.

MSF has signed agreements with the Brazilian Ministry of Health (MoH) and Fiocruz, a public research body funded by the Brazilian government. The former established a cooperative agreement involving technical collaboration on the response to HIV/AIDS, so that MSF and the Brazilian MoH can collaborate to improve the delivery of treatment in resource-poor settings. The agreement with Fiocruz allows MSF to purchase antiretroviral drugs produced by FarManguinhos, the Brazilian national pharmaceutical producer, which is part of Fiocruz.

An innovative aspect of this arrangement is that the money MSF pays will go directly into research and development for AIDS and neglected diseases such as sleeping sickness, Chagas Disease and malaria (all diseases for which current treatment options are inadequate).

MSF is currently using the antiretroviral drugs AZT, 3TC, co-formulated AZT/3TC, and nevirapine produced by FarManguinhos. By using these drugs the price per patient per day falls from US\$3.20 to US\$1.55.

In 1996, in response to pressure from civil society, the Brazilian government began providing free access to antiretroviral therapy to people with HIV/AIDS. This policy has allowed more than 100,000 people to receive antiretroviral therapy and reduced AIDS-related mortality by more than 50%. Between



1997 and 2000, antiretroviral treatment has saved the Brazilian government \$677 million on hospitalisations averted and treatment for opportunistic infections averted.

South Africa could launch a similar programme. To do so, the government needs to have access to the lowest cost medicines, whether they come from multinational pharmaceutical companies or from generic producers. This means both taking advantage of offers from multinational companies and being willing to seek compulsory licenses. These licenses can be used to produce these drugs locally or import them and are an important way to stimulate competition, which is a powerful tool to reduce prices.

## Drug companies and TRIPs

Oxfam GB

While people in rich countries enjoy the benefits of ever-improving drug treatments, in poor countries 30,000 people die every day because effective medicines are too expensive or simply not available. Now the World Trade Organisation's Trade Related Aspects of Intellectual Property Rights ? TRIPs, ? has set a worldwide standard for protecting patents: at least 20 years patent protection on all forms of products and processes. And that includes medicines.

Trans-national drug companies helped to set up, and will benefit directly from, TRIPs. The companies hold more than 90 per cent of drugs patents, and so effectively control the global market.

Patents keep medicine prices high, so poor people can't afford them. And people in the Third World lose out in other ways too. Drug companies argue that the protection of patents enables them to recoup the costs of the research and development that went into their production. Patents do encourage innovation but the super-profits they generate are concentrated in rich country markets. Poor people should not pay the penalty for protecting those markets.

Until recently, cheaper copies (or "generics" ) of life-saving medicines have been produced by some companies, many of which are based in poor countries. These have offered poor people an affordable alternative to expensive brand-name medicines. The new patent rules threaten this practice because drug companies will be able to use TRIPs rigidly to enforce their patents.

Oxfam is calling for the WTO to reform TRIPs so that Third World governments have the unambiguous right to obtain the cheapest possible life-saving medicines, without facing the threats of legal challenges or trade sanctions. Oxfam is calling on the pharmaceutical industry, including GlaxoSmithKline and Pfizer, to support the reforms.