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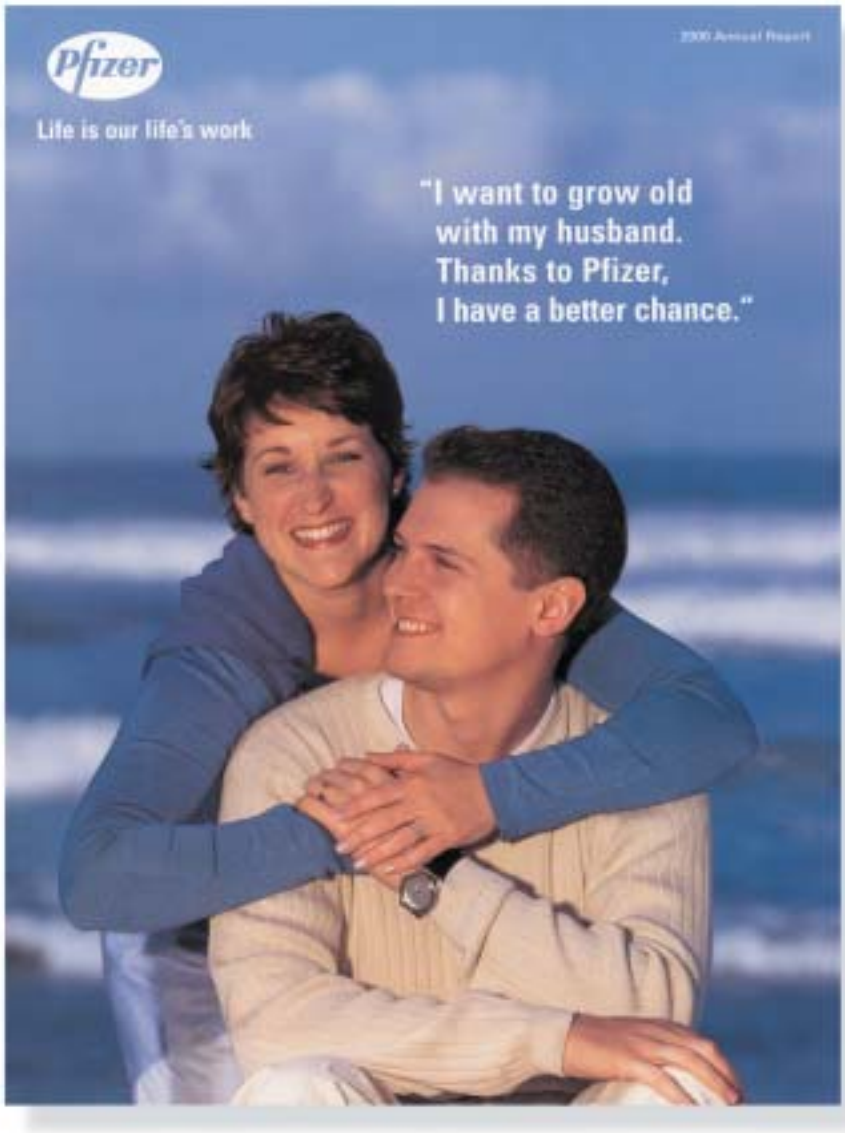
Oxfam Briefing Paper on

Pfizer



Preventing the cure:

Corporate lobbying and fair access to medicines

Oxfam

CUT THE COST

Oxfam Company Briefing Paper

Pfizer

Formula for Fairness:

patient rights before patent rights

Oxfam

Oxfam's Company Briefing Papers

This is the second in a series of briefing papers analyzing the human development impact of multinational corporations (MNCs). It is part of Oxfam International's Trade Campaign. The series examines the links between trade and poverty eradication and illustrates the challenges facing industry as a whole in contributing more systematically to the reduction of poverty and suffering. It also identifies the reputation risks posed to firms operating in a global economy in which over 3 billion people have extremely limited purchasing power – a situation that makes it impossible for the market alone to respond adequately to the needs of the poor.

One of the defining features of globalization has been the introduction of new and more stringent international agreements to guarantee minimum trading standards. A rules-based system to provide developing countries with a chance to operate on a level playing field is needed but does not yet exist. On the contrary, there is evidence that the rules agreed upon so far favor rich countries and the companies operating from within them.

This second paper in the series (following "Dare to Lead: Public Health and Company Wealth," Oxfam briefing paper on GlaxoSmithKline) continues our scrutiny of the link between trade rules and poor people's access to medicines. The unfolding global health crisis and recent changes to international rules combine to make this a priority development issue. The global burden of ill health is borne disproportionately by developing countries. Any changes to trade rules that have an impact on health must diminish the problems these countries already experience in delivering safe and affordable medicines to the poor. Recent changes, however, risk having the opposite effect.

Pharmaceutical companies operate in a marketplace in which Research and Development (R&D) priorities are de-linked from global health needs, and in which the poor are sidelined in corporate marketing strategies and sales profiles. Recent campaigns and media coverage of the issue of access to medicines has led to growing public concern about the applicability of a global patent system to the needs of poor countries. Some progress has been made, including a range of price cuts and the withdrawal by the pharmaceutical industry from the South Africa Court Case as well as the withdrawal by the U.S. government from the Brazil World Trade Organization (WTO) dispute.

However, these advances should not distract from the need for a reform of the Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement and increased commitment to other global health initiatives. There are many factors preventing access to medicines. This paper focuses on price and on the need for more research into diseases of the poor as being the most significant parts of the puzzle that lie within the power of companies to influence. It is one of the briefing papers produced by Oxfam International in its Cut the Cost Campaign. The others include *"Patent Injustice: How World Trade Rules Threaten the Health of the Poor"*; a technical paper, *"Fatal Side Effects: Medicine Patents Under the Microscope"*; and *"Implausible Denial: Why the Drug Giants' Arguments on Patents Don't Stack Up."* There are also a number of country-specific briefing papers on South Africa, Brazil and Thailand. These papers are available at **www.oxfam.org.uk/cutthecost**.

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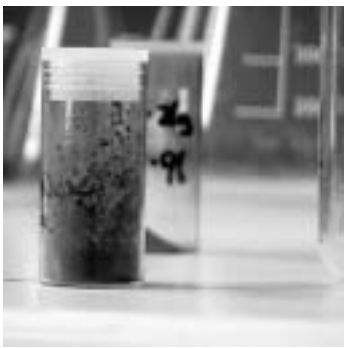


MARK BUSHNELL

Pharmaceutical companies operate in a marketplace in which Research and Development (R&D) priorities are de-linked from global health needs

Executive **Summary**

Why Pfizer?
The agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) – the new twenty-year patent regime that the World Trade Organization (WTO) requires all member states to implement – is likely to keep prices of vital new medicines higher than they otherwise would be and thereby exacerbate the vast health disparities between rich and poor countries. Meanwhile, accusations of insensitivity to the plight of the world's poor have increasingly put the pharmaceutical industry on the defensive. Against this background, Pfizer is a natural subject for our second company briefing paper. As the industry's largest company, what it says and does is highly influential both within the industry and beyond. Yet, it has consistently lobbied for stronger patent protection, including TRIPS, while denying in a meeting with Oxfam the obvious negative implications for poor people's access to life-saving drugs. Pfizer, like other leading companies, has various philanthropic programs, but in Oxfam's opinion these remain inadequate in relation to the scale of the crisis in the developing world.

A New Pharmaceutical Giant
Pfizer is a huge, highly profitable, and rapidly-growing company. Boosted by its merger in 2000 with Warner-Lambert, its sales last year were almost US$30 billion, pre-tax income is expected to be over $13 billion in 2002, and its US$266 billion market value is larger than, for example, the combined national incomes of the eighteen biggest economies in sub-Saharan Africa. Its sales in the poor countries in which most of the world's population lives are, like those of other leading pharmaceutical companies, relatively small. However, Pfizer does have – in its infectious diseases business, in particular – a range of products and an accumulated expertise that could be of enormous benefit if applied more concertedly to the health problems of the developing world.

From Bad to Worse – the Health Divide and TRIPS
Diseases that are under control in the developed world cause millions of premature deaths in the developing world. The reasons are various, but limited access to life-saving drugs that are widely available in rich countries is an important one. Affordability is one of the factors restricting access, and patent protection is a key factor influencing the affordability of new drugs. This analysis makes particularly alarming the marked strengthening of patent protection in poor countries that will result from implementation of the TRIPS agreement. TRIPS does allow for exceptions in theory, but the safeguard provisions are proving very difficult to operate in practice in the face of legal and other pressures from powerful companies and their governments. Indeed, the U.S. government has pressured a number of countries into adopting "TRIPS-plus" legislation.

The Health Divide – Response of Pfizer and the Industry

Despite owning three important drugs for infectious diseases – the antifungal Diflucan, the antibiotic Zithromax, and the antiretroviral Viracept – Pfizer, unlike a number of its competitors, has shown little flexibility on pricing and patent enforcement in poor countries. Where it has patents, it appears to adopt a broadly uniform pricing strategy, and its policy is not to issue licenses to generic manufacturers. The result is that its drugs are often priced beyond the means of poor people and their governments. Pfizer's main response to the health crisis in the developing world has been to undertake limited donations (for example, Zithromax for one particular disease in a handful of countries). While Oxfam does welcome initiatives of this kind – and there are now many similar programs being undertaken by the leading pharmaceutical companies, partly in response to public pressure – in our opinion they are, taken together, no substitute for more systematic policies aimed at making medicines more widely available.

Power and Pressure – Pfizer's Lobbying

Pfizer has lobbied vigorously and successfully in support of its commercial interests; notwithstanding the public health implications. Its chief executive is the chairman of the Pharmaceutical Research and Manufacturers of America (PhRMA), the most powerful pharmaceutical industry lobby in the U.S. It has close links with government, and its personnel occupy a number of important policy-shaping roles. It was a driving force in putting intellectual property on the trade agenda and therefore was instrumental in the eventual adoption of TRIPS. It has played a leading role in encouraging the U.S. administration to use bilateral negotiations and unilateral economic sanctions – including making suggestions as to who should be placed on the U.S. government's 301 Priority Watch List – against countries that it believes offer inadequate patent protection.

Time for Action

Oxfam fully accepts that patents can be an important incentive for R&D, but we believe the "one-size-fits-all" TRIPS system has huge failings and must be reformed. Although the pharmaceutical industry continues to fight hard in defense of lengthy and globally uniform patent protection, we believe that many of the arguments it routinely uses in support of its case are flawed. Box 2 on pages 40-41 explains precisely why. We urge the individuals at the helms of the leading pharmaceutical companies to take much more seriously the responsibility bestowed upon them by the fact that they have it in their power to save many thousands of lives at little or no cost to themselves or their companies. With goodwill on all sides, substantial progress is possible this year.

The report ends with the following **recommendations** to the Pfizer management team.

In the interests not just of the poor people of the developing world, but also of the long-term health of the industry itself, Pfizer should adopt a more constructive leadership role, both through PhRMA and independently of PhRMA. We call on Pfizer to:

- recognize that the price of life-saving medicines in developing countries is linked to patents and TRIPS.
- refrain from using its lobbying power to exert pressure for TRIPS-plus regimes in all trade agreements including via USTR's Section 301 mechanism.
- acquiesce in modifications to TRIPS that achieve a greater balance between public health needs and the interests of companies and abide by the modified rules.
- abstain from enforcing patent rights in developing countries where to do so yields little or no commercial advantage in the country concerned and look favorably on requests for voluntary licenses where there are urgent public health needs. Patents confer the right to enforce exclusivity but do not impose the obligation to do so.
- where exclusivity is enforced, and as a *quid pro quo* for measures to prevent low-price drugs from leaking into rich country markets and the creation of the UN Global Health Fund, accept the establishment of a competitive global tiered pricing mechanism.
- participate creatively in research programs aimed at poor-country diseases by increasing its in-house proprietary research in response to a global R&D fund; contributing to the proposed global research fund.

TRIPS is likely to keep prices of vital new medicines higher than they otherwise would be and thereby exacerbate the vast health disparities between rich and poor countries

J. L. QUINTANO/OXFAM

Section 1

Introduction & Overview

Summary

The agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) – the new twenty-year patent regime that the World Trade Organization (WTO) requires all member states to implement – is likely to keep prices of vital new medicines higher than they otherwise would be and thereby exacerbate the vast health disparities between rich and poor countries. Meanwhile, accusations of insensitivity to the plight of the world's poor have increasingly put the pharmaceutical industry on the defensive. Against this background, Pfizer is a natural subject for our second company briefing paper. As the industry's largest company, what it says and does is highly influential both within the industry and beyond. Yet it has consistently lobbied for stronger patent protection, including TRIPS, while denying in a meeting with Oxfam[1] the obvious negative implications for poor people's access to life-saving drugs. And although, like other leading companies, Pfizer has various donations and philanthropic programs, in our opinion these remain inadequate in relation to the scale of the crisis in the developing world.

Why Pfizer?

Oxfam published a detailed briefing paper on the U.K. pharmaceutical giant GlaxoSmithKline in February 2001.[2] This was the first in a series of papers on the role of transnational corporations in the developing world. We have chosen its U.S. counterpart, Pfizer, as the subject of our second company briefing because:

- following its absorption of Warner-Lambert, Pfizer is **the biggest pharmaceutical company in the world**. It sells seven of the world's top thirty drugs and has the largest research and development (R&D) budget in the industry.
- Pfizer has a **new chairman and chief executive officer** (CEO), who is also the new chairman of PhRMA, the most powerful pharmaceutical industry lobby in the U.S.
- there is **growing international concern** about the health crisis in developing countries, and a risk that the crisis will be exacerbated in the future by the TRIPS agreement within the WTO – that Pfizer was instrumental in bringing into existence. This concern, which United Nations Secretary-General Kofi Annan has described as "a worldwide revolt of public opinion,"[3] was vividly illustrated by the scale of international opposition that in April 2001 forced thirty-nine leading drugs companies to withdraw their lawsuit against the South African government's Medicines Act.
- the large **pharmaceutical companies are now on the defensive**, and Pfizer's size and visibility mean that – even though it was not involved in the South Africa case – it will necessarily play a central role in the continuing debate on public health and trade rules. Close scrutiny of its decisions about access to its own products in poor countries and about the allocation of its huge R&D budget is inevitable. It will also be monitored for the extent to which it exercises socially enlightened leadership in influencing the rest of the industry and the U.S. government.
- Pfizer has played an important role in influencing U.S. government **enforcement of intellectual** property through the use of bilateral negotiations and unilateral economic sanctions, including the "Special 301" provision.
- Pfizer **claims that patent rules have nothing to do with access** to affordable life-saving medicines, yet the reality is that –

although the international campaign for access to drugs in developing countries has recently gained traction from the outcome of the South Africa case and the U.S. government's decision to drop its complaint against Brazil at the WTO "court" – the TRIPS agreement still threatens to frustrate efforts to widen access by making cheap generic drugs available.

⋯⁘ like most other pharmaceutical companies, Pfizer has launched a number of well-publicized **philanthropic initiatives**, the most recent ones coming on the heels of intense international scrutiny and negative publicity. But in Oxfam's opinion, even generous programs such as these are an inadequate response to the health crisis confronting poor countries.

Contents of Rest of Paper

This paper focuses specifically on issues pertaining to the developing world, and is not intended to be a comprehensive review of the operations of Pfizer or the industry.

Section 2 – "A New Pharmaceutical Giant" – gives a brief profile of Pfizer.

Section 3 – "From Bad to Worse – The Health Divide and TRIPS" – first describes the depth of the divide between poor and rich countries in the incidence of disease and premature death and in levels of access to affordable life-saving medicines. It then outlines the TRIPS regime, which greatly strengthens drug companies' patent protection in developing countries. It shows that patents keep prices high and that high prices are, in turn, a key factor limiting poor people's access to life-saving medicines (especially newer, and possibly more effective, patent-protected drugs). The failure to access affordable medicines is, in turn, a key factor in the massive disparity in the rates of disease and early death between rich and poor countries. While disease prevention, especially as to the HIV/AIDS pandemic, is obviously vital, this paper focuses on patents and price as the issues over which companies have the greatest control.

Section 4 – "The Health Divide: Response of Pfizer and the Industry" – looks at the efforts to date of pharmaceutical companies, including Pfizer, to improve poor people's access to life-saving medicines in developing countries. Some companies do now acknowledge that it is in their self-interest to act in a socially responsible manner. However, on the whole, the industry's price cuts and philanthropic responses have been ad hoc and piecemeal. Although valued by the individuals who benefit, this response still only scratches the surface of what *The Economist* has called the "new war on drugs – the struggle to speed the flow of pharmaceuticals from rich to poor."[4]

Section 5 – "Public Pressure: Pfizer's Lobbying" – looks at the company's close links with government and its central role both in the conception of the TRIPS regime and in the vigorous global enforcement of intellectual property rights through the WTO mechanisms. Pfizer has been extremely successful in lobbying for enhanced patent protection, yet continues to push for more, despite the potentially negative impact on public health in poor countries.

Section 6 – "Time for Action" – reviews a systematic and structural alternative to the trade rules that are currently failing the people of the developing world. TRIPS can and should be reformed in ways that will both permit sufficient patent protection to provide incentives for R&D and, at the same time, allow governments in poor countries to meet urgent public health needs. These reforms should be combined with a large injection of resources into health by the international community. Cooperation in such measures could do much to repair the reputational damage inflicted on the industry by its slow and limited response to the problem and could reduce the risk, from the industry's perspective, of harmful legislation to which unpopular industries are always vulnerable.

Section 7 – "Recommendations" – lists steps that Oxfam believes should be taken by governments, international institutions, and Pfizer. This section offers proposals for Pfizer to advance toward its stated desire to do "more good for more people than any other company on the planet."

MARK BUSHNELL

Pfizer has consistently lobbied for stronger patent protection, including TRIPS, while denying in a meeting with Oxfam[1] the obvious negative implications for poor people's access to life-saving drugs

Section 2

A New **Pharmaceutical Giant**

MARK BUSHNELL

Pfizer's market value is larger than the combined national incomes of the eighteen biggest economies in sub-Saharan Africa

Summary

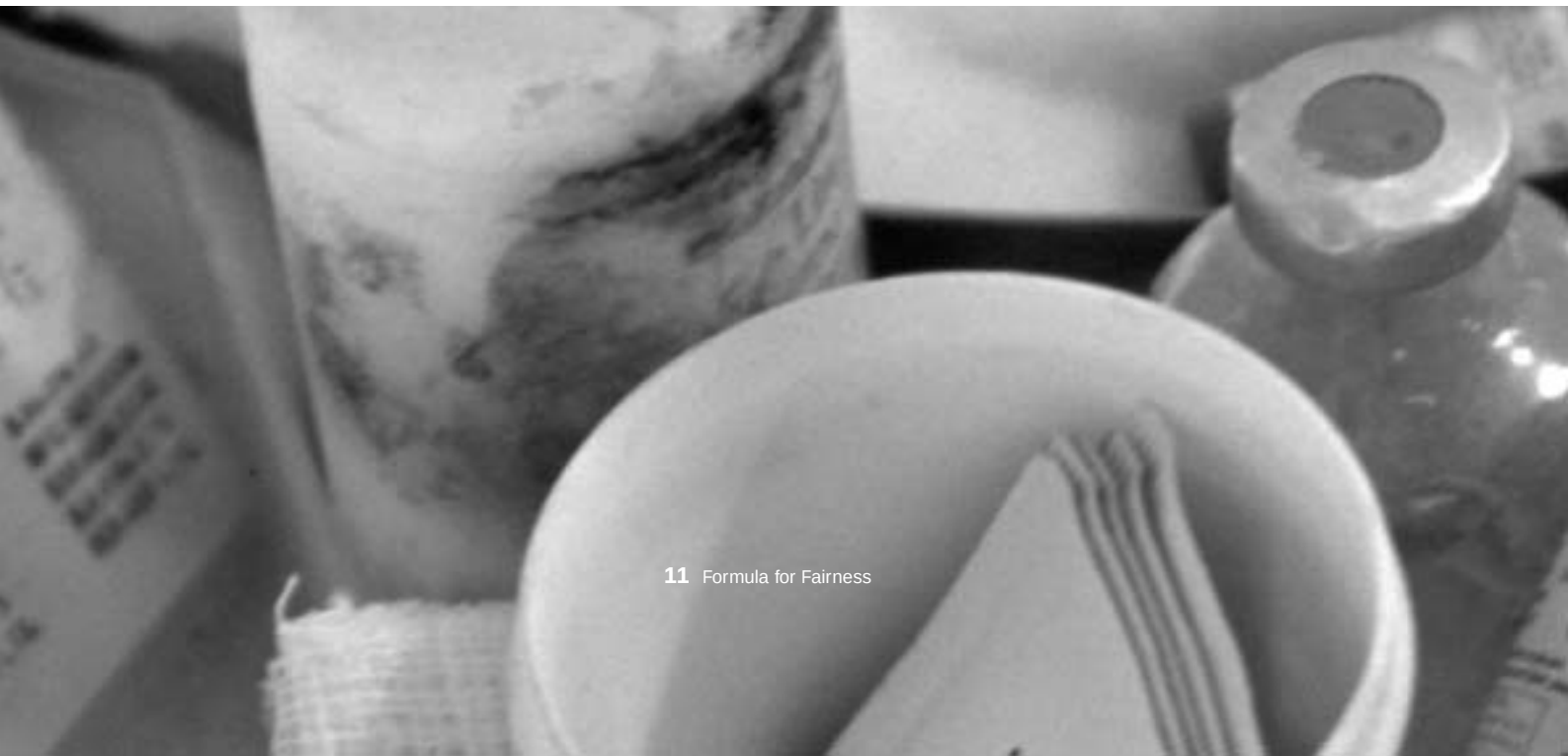
Pfizer is a huge, highly profitable, and rapidly growing company. Boosted by its merger in 2000 with Warner-Lambert, its sales last year were almost US$30 billion, pre-tax income is expected to be over US$13 billion in 2002, and its US$266 billion market value is larger than, for example, the combined national incomes of the eighteen biggest economies in sub-Saharan Africa. Its sales in the poor countries in which most of the world's population lives are, like those of other leading pharmaceutical companies, relatively small. However, Pfizer does have – in its infectious diseases business in particular – a range of products and an accumulated expertise that could be of enormous potential benefit if applied more concertedly to the health problems of the developing world.

A New Industry Leader

"We are striving to be the company that does more good for more people than any other company on the planet." – Dr. Henry McKinnell, CEO of Pfizer, April 2001

After its merger with Warner-Lambert in June 2000, Pfizer – a U.S. company headquartered in New York City – became the world's biggest pharmaceutical company by sales, ahead of GlaxoSmithKline (GSK), Merck, AstraZeneca, and Aventis.[5] Employing 12,000 researchers, it is the largest pharmaceutical R&D spender in the world. Its total R&D budget for 2001 is around US $5 billion.[6]

The Warner-Lambert merger was part of a broader trend that consolidates corporate power in fewer hands at unprecedented levels. Pfizer's pharmaceutical sales, including Warner-Lambert, were US$22.6 billion last year, giving it a world market share of



around 7%.[7] Sales including animal health products and consumer products (such as Sudafed and Zantac 75) were US$29.6 billion. Pfizer's global sales and marketing organization employs more than 30,000 people. The company has employees in approximately 90 countries. Pfizer's principal business units are located in developed countries, mainly in the United States. Its products are sold in more than 150 countries around the world, with almost 70% of sales in the U.S. and Japan, and much of the rest in Europe. This typifies the drug market concentration in rich countries.

Production costs accounted for only 17% of sales in 2000. Hence, even after R&D of US$4.4 billion in that year, and selling, informational, and administrative expenditures of US$11.4 billion (including US$3.4 billion in advertising), Pfizer's income before taxes and minority interests was US$8.9 billion,[8] or 30% of sales. This result was helped by post-merger cost savings of US$430 million and nearly 4,000 layoffs. On the same basis, net income grew by 25% to US$6.5 billion.

Helped by double-digit sales growth and substantial further cost savings, the company expects earnings growth of at least 25-27% in 2001 (growth in the first quarter of the year was 32%) and at least 20% in 2002, implying pre-tax income of over US $13 billion next year. Partly reflecting these targets – the achievement of which will be the responsibility of the new chairman and chief executive officer, Henry McKinnell – Pfizer enjoys a significantly higher price/earnings ratio than the industry average. Its stock market value is now US$266 billion.[9] To put this into perspective, Pfizer's market value is almost twice the gross national product (GNP) of South Africa, the largest economy in sub-Saharan Africa, and exceeds the combined GNPs of the eighteen biggest economies in that region.[10]

Morgan Stanley Dean Witter had the following to say about Pfizer: "Management is on record as saying Pfizer will grow at least 25% over the next several years. We feel confident in the company's ability to achieve these targets".[11]

JONATHAN RAINSFORD

MARK BUSHNELL

Pfizer is uniquely positioned to influence the policies of governments and international organizations and to lead other companies by its example

Therapeutic Strengths

Eight Pfizer products had sales in 2000 of over US$1 billion, including three over US$2 billion and two over US$3 billion. Its cholesterol-reduction drug Lipitor (atorvastatin) – with sales of over US$5 billion – was the world's second-top-selling pharmaceutical product.

Pfizer's sales breakdown by therapeutic area reflects the industry's disproportionate focus on diseases in rich countries. Its two biggest product categories are cardiovascular disease and central nervous system disorders, which are prevalent in developed nations such as the U.S. Its infectious disease category represents 16% of total human pharmaceutical sales. The top three products in this category are:

- the world's top-selling prescription antifungal **Diflucan** (fluconazole), the uses of which include treatment of life-threatening opportunistic infections common in HIV/AIDS, notably the brain infection cryptococcal meningitis.
- the world's top-selling protease inhibitor for HIV/AIDS, **Viracept** (nelfinavir), which is sold by Pfizer in North America and licensed to Roche in exchange for a royalty elsewhere (apart from Asia, where Japan Tobacco has the rights).
- and the macrolide antibiotic **Zithromax** (azithromycin), which is the most prescribed branded oral antibiotic in the U.S. and treats, among other things, most respiratory infections in adults and children. The once-daily dose for 3-5 days has been key to the product's success.

These product lines suggest that Pfizer has considerable expertise that is of critical significance for developing countries today, particularly in the category of infectious disease. Pfizer's R&D pipeline includes around 150 research programs in nineteen therapeutic areas. Among the compounds in late-stage R&D are two with significant potential to treat infectious diseases common to developing countries. Vfend (voriconazole) is a broad-spectrum antifungal intended to complement Diflucan. Capravirine is an antiretroviral expected to be as effective as the triple therapy combination of Viracept and GSK's AZT and 3TC, used to combat HIV/AIDS.

A Uniquely Influential Role

As a US company that leads the world pharmaceutical industry, and whose chairman and CEO is chairman of PhRMA, Pfizer is uniquely positioned to influence the policies of governments and international organizations and to lead other companies by its example. In that sense, certainly, Pfizer's boast that it"can make more difference to human life than any company has ever made before"[12] is true.

Pfizer will increasingly become embroiled in the burgeoning debate about the social responsibility of pharmaceutical companies in the face of nearly 40,000 people a day dying from treatable infectious diseases. Indeed, the company is already involved in a number of controversies relating to affordable access to its own patent-protected life-saving medicines (see section 4). As an industry leader, Pfizer bears a special obligation to shape socially enlightened policies that could improve the lives of poor people around the world, and to do "more good for more people than any other company on the planet."

Section 3

From bad to worse - the health divide and trips

Summary

Diseases that are under control in the developed world cause millions of premature deaths in the developing world. The reasons are various, but limited access to life-saving drugs that are widely available in rich countries is an important one. Affordability is one of the factors restricting access, and patent protection is a key factor influencing the affordability of new drugs. This analysis makes particularly alarming the marked strengthening of patent protection in poor countries that will result from implementation of the TRIPS agreement. TRIPS does allow for exceptions in theory, but the safeguard provisions are proving very difficult to operate in practice in the face of legal and other pressures from powerful companies and their governments. Indeed, the U.S. government has pressured a number of countries into adopting "TRIPS-plus" legislation.

patent protection is a key factor influencing the affordability of new drugs

CATALINA ANECA

Death and Disease – The Gulf Between Rich and Poor

The sheer scale of the global health divide is illustrated by two arresting comparisons:[13]

- The mortality rate among children under five averages 75 per 1,000 worldwide, but ranges from just 6 in high-income countries to 151 in sub-Saharan Africa.
- Worldwide, life expectancy at birth averages 65 for men and 69 for women. But this conceals a huge disparity between high-income countries, where it is 75 for men and 81 for women, and the low- and middle-income countries of South Asia, where it is 62 and 63, respectively. Sub-Saharan Africa is even farther behind, with life expectancy at 49 for men and 52 for women.

Much of the explanation lies in the high death rates in developing countries from infectious diseases that have been effectively controlled in rich countries. Table 1 shows causes of death by region. In Africa, infectious and parasitic diseases account for 60% of deaths. In Europe, by contrast, they account for just 5% of total deaths, while over 70% are caused by cancer and cardiovascular disease (both of which are correlated with age and lifestyle factors, and together account for fewer than 15% of deaths in Africa).

Table 1: Deaths by Cause in WHO Regions, Estimates for 1999 (%)

Cause of death	World	Africa	Americas	Eastern Med	Europe	SE Asia	Western Pacific
Infectious/Parasitic Diseases							
Tuberculosis	3	3	1	3	1	5	3
HIV/AIDS	5	21	1	1	0	3	0
Diarrheal Diseases	4	7	1	7	0	7	1
Childhood Diseases	3	7	0	5	0	4	0
Malaria	2	9	0	1	0	0	0
Respiratory Infections	7	10	5	8	3	11	4
Tropical Diseases & Other	1	3	1	2	1	1	0
	25	**60**	**11**	**26**	**5**	**31**	**9**
Other Causes							
Malignant Neoplasms (cancer)	13	5	18	6	20	8	18
Cardiovascular Diseases	30	9	34	32	51	29	32
Injuries	9	7	10	10	8	9	11
Other	23	19	27	26	16	23	30
	75	**40**	**89**	**74**	**95**	**69**	**91**

Source: Adapted from WHO World Health Report 2000, Annex 3

These totals may not add to 100% due to rounding

While scientific progress continues apace in the developed world – the mapping of the human genome, for example, offers scope for a quantum leap in targeted "individualized" drug treatment – the story elsewhere is very different. Of the estimated 40 million deaths (around 1,600 per hour) from infectious and parasitic diseases in 1999, most were of poor people in developing countries, including 6.3 million in Africa and 4.4 million in Southeast Asia. More than half were of children under five. Six diseases – pneumonia, diarrhea, HIV/AIDS, malaria, measles, and tuberculosis (TB) – account for most of these deaths, killing mainly children and young adults.

and Poor

Two relatively new factors will likely worsen this already bleak picture:

- **AIDS epidemic**. More than 95% of the nearly 15,000 new HIV infections per day occur in developing countries. Of the 36.1 million people estimated to be living with HIV/AIDS at the end of 2000, 25.3 million were in sub-Saharan Africa. In this region, the infection rate among people 15 to 49 is estimated at 8.8%, compared with well under 1% in Western Europe and North America. Of the 21.8 million cumulative deaths so far from AIDS, more than 15 million have been in sub-Saharan Africa, where in 1999 a massive 9% of HIV-positive people died from AIDS or related diseases. If deaths had occurred at the much lower European or U.S. rates (1.3% and 2.4%, respectively), over 1.5 million fewer Africans would have died of AIDS in that year alone.[14] HIV/AIDS is also on the increase at alarming rates in South Asia and Latin America. More than 4 million have been infected in India alone.
- **Drug resistance**. Chloroquine, previously the first-line treatment for malaria, is now ineffective in 80 of the 92 countries where malaria is a serious problem. In some countries, up to half of meningitis and pneumonia cases are now resistant to penicillin. The emergence of drug-resistant strains of, among other things, TB, malaria, pneumonia, diarrhea, cholera, HIV, gonorrhea, and other sexually transmitted infections is a growing threat across the world. A key culprit in developing countries is sub-optimal drug use, especially truncated courses of antibiotics, that result from poverty and high prices. The consequences of resistance will be most severe in developing countries, given that the emergence of resistance to first-line treatments means that much more expensive second- and third-line treatments become necessary for treatment to be effective. For example, a six-month treatment course for TB usually costs around US$20, but with multi-drug resistant TB, the cost can leap to US$2,000+.[15]

Much of the developing world is caught in a vicious circle: poor health causes poverty and poverty causes poor health. According to an April 2000 WHO-sponsored report, malaria has slowed Africa's economic growth by 1.3% per annum. Sub-Saharan Africa's GDP "would be up to 32% greater ... if malaria had been eliminated 35 years ago. This would represent up to $100 billion added to sub-Saharan Africa's current GDP of $300 billion. This extra $100 billion would be, by comparison, nearly five times greater than all development aid provided to Africa [in 1999]"[16] Malaria-free countries average three times higher GDP per head than malarious countries, even after allowing for differences in government policy, geographical location, and other factors affecting economic well-being. Similarly, the ravaging of Africa by HIV has ominous implications for macroeconomic growth. The World Bank estimates that per capita growth rates in sub-Saharan Africa, were reduced by 0.7% p.a. between 1990 and 1997, due to the AIDS epidemic.[17] Another World Bank study suggests that South Africa's GDP will be 17% lower in 2010 than it would have been without the effect of AIDS. A recent Harvard study suggests that these predictions even underestimate the negative impact because they do not take feedback effects into account, including falling worker productivity, declining savings and investment, and rising business costs.[18]

The causes of the public health crisis in developing nations are complex. Poor nutrition, inadequate water and sanitation, armed conflict, and logistical difficulties are all important in explaining the health divide. However, access to effective drugs is also a fundamental factor.

MARK BUSHNELL

The World Bank estimates that per capita growth rates in sub-Saharan Africa, were reduced by 0.7% p.a. between 1990 and 1997, due to the AIDS epidemic.[17]

At one level, the problem is that in some cases the necessary armory of drugs simply does not yet exist. The commercial pull of rich country markets has led to a paucity of research into affordable therapies, including vaccines, for the diseases affecting poor people. Only 10% of global health research is devoted to health problems in developing countries, and only 2% is devoted to R&D into AIDS, malaria, acute respiratory infections, diarrheal diseases, and TB combined.[19] There is, therefore, a compelling need for more R&D into these under-researched disease areas and particularly into treatments for resistant strains of the common killer diseases.

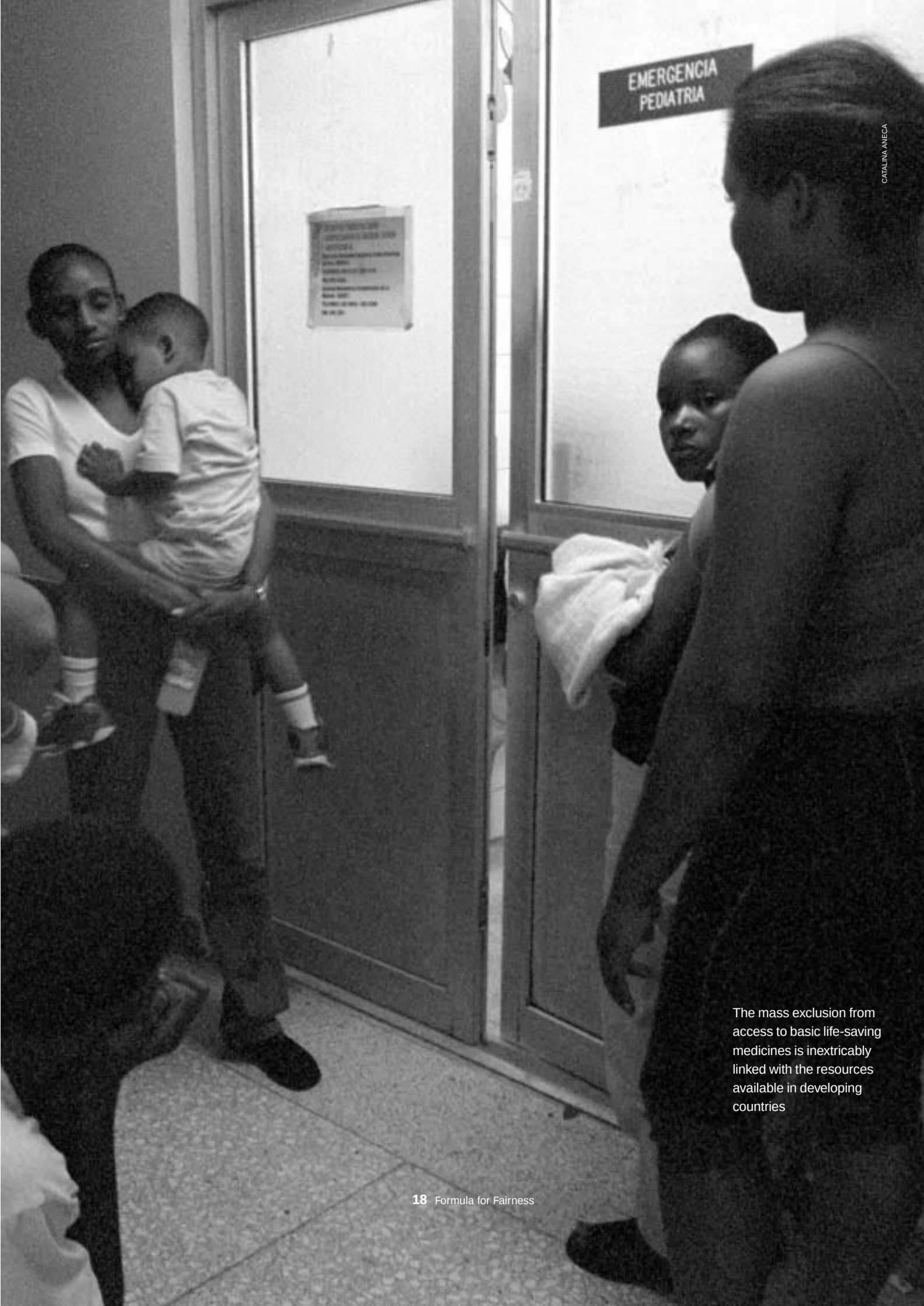
Effective drugs do exist, however, for many developing-country diseases, and yet more than one-third of the world's population – and more than half of the population of Africa - do not have regular access to even basic medicines to treat these diseases.[20]

The mass exclusion from access to basic life-saving medicines is inextricably linked with the resources available in developing countries. World Health Organization (WHO) statistics show that total per capita annual health expenditure – public plus private – is less than US$100 in sixty-six countries and less than US$50 in thirty countries, compared with US$3,724 in the U.S.[21] Public expenditure on pharmaceuticals is less than US$10 per head in sixty-one countries.[22]

In some cases, low government expenditure on health reflects lack of political commitment to public health and inappropriate prioritization of resources. Usually, however, it simply reflects a lack of money. For example, excluding South Africa, average GNP per head in the top twenty economies in sub-Saharan Africa was US$322 in 1999.[23] In such circumstances, even the best-intentioned governments can spend very little on health, and as a direct result, millions of poor people die each year from diseases that, according to the WHO, could in many cases be prevented at a cost of less than $5 per life saved.[24]

The gap between public provision and what is necessary is to some extent filled by private out-of-pocket expenditure. According to one source, 80% of people in developing countries pay directly for some or all of their own medicines.[25] But this can involve considerable hardship. Purchases of pharmaceuticals are often at the expense of food and education, and financial constraints inevitably result in under-consumption. The consequences are ineffective treatment and the growth of drug resistance.

$5 per life saved



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The mass exclusion from access to basic life-saving medicines is inextricably linked with the resources available in developing countries

MARK BUSHNELL

TRIPS requires the domestic intellectual property regimes of all 141 current WTO member states to include patent protection of at least twenty years from the date of filing on all new technologies, including pharmaceuticals

TRIPS – Globalization of a Rich-Country Patent System

The high cost of drugs, combined with low incomes in developing countries, is clearly a key factor in disparate access to life-saving medicines and in disease and death rates between rich and poor countries. Drug prices are influenced by a wide range of factors, including distribution costs, tariffs, exchange rates, and local economic circumstances. However, the extent to which there is competition in the pharmaceutical market plays a vital role in determining prices. Prices tend toward the lowest achievable when there are five or more competing equivalent products on the market.[26] Patent protection limits the level of competition for a specified period, allowing prices and profits to be higher during that time, as a means of encouraging innovation.

Until 1995, every country, in framing its patent regime, was free to strike its own balance between encouraging innovation and maximizing the availability of affordable medicines to its populace. Many developing countries chose to use this freedom to exempt drugs from patenting or to grant only limited protection (e.g., a maximum of five years, or patents on processes but not products), thereby allowing low-price generic versions of new products to enter the market within a few years of launch of the original product. Indeed, many of today's rich countries did not grant patent protection during earlier stages of their development, choosing to wait first for the emergence of local pharmaceutical industries before enforcing patents in their own markets.

The new global intellectual property regime enshrined in the WTO's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) is very different. Championed by the U.S. government and the pharmaceutical industry, (led by Pfizer – see section 5), the TRIPS agreement formed part of the final Act of the Uruguay Round of trade negotiations that was signed in 1994 and that involved the formation of the WTO – the successor to the General Agreement on Tariffs and Trade – in January 1995.

TRIPS requires the domestic intellectual property regimes of all 141 current WTO member states (and any future new members) to include patent protection of at least twenty years from the date of filing on all new technologies, including pharmaceuticals, which meet the standard criteria of novelty, inventiveness, and industrial applicability. Industrialized countries had to comply with this requirement by 1996. Although seventy developing countries had until 2000 to comply, and the rest have until either 2005 or 2006 (with possible extensions on a case-by-case basis), they have been required meanwhile to offer "market exclusivity" to new products – effectively equivalent to patent protection – pending implementation of TRIPS-compliant domestic legislation. In the event of alleged non-compliance, a complex and costly WTO dispute mechanism can be triggered. The potential penalty for non-compliance with an adverse adjudication of the Dispute Settlement Body is trade sanctions against the recalcitrant country by the complaining countries.

The new requirement of at least twenty years of patent protection represents a substantial increase in many developing countries. To meet concerns of developing countries, the agreement is subject to certain public interest safeguards and exceptions. Some observers do regard these safeguard provisions as adequate. Indeed, Pfizer itself is among them. However, Oxfam's view is that these safeguards are piecemeal, ambiguous, and difficult to administer, especially because of the threat of legal challenge and use of the WTO dispute procedures. For example:

- Article 8 of TRIPS holds that member states "may, in formulating or amending their laws and regulations, adopt measures to protect public health ... and to promote

20 years

of patent protection represents a substantial increase in many developing countries.

the **public interest** in sectors of vital importance....” However, it seriously undermines this by adding the requirement that such measures must be “consistent with the provisions of this Agreement.”

- Article 6 in effect allows **parallel importing** of patented products available more cheaply elsewhere in the world. However, the globalization of patent terms in the TRIPS agreement, which reduces pricing pressure from generics, is likely to stem significant opportunities for savings from parallel imports.
- Article 31 allows national legislation to give governments the right, in specific circumstances, to grant a **compulsory license** to third parties to manufacture a generic version of a product without the authorization of the patent holder. However, the circumstances in which this may happen are limited, the procedures are cumbersome, undefined “adequate remuneration” must be paid to the patent holder, and experts disagree on whether this article permits licenses to be granted to companies in another country or whether manufacture must be domestic (which would obviously pose a problem for the many developing countries without a domestic generics industry). A “national emergency” can be invoked to accelerate the process, but the term is not defined.

Under the strict interpretations pushed by the U.S. government and the industry, both Articles 6 and 31 give wide scope for dispute procedures.

Pharmaceutical corporations, and some industrialized country governments have pressured developing countries not to use versions of even these limited safeguards – for example, in the lawsuit mounted by the industry against the South African government and in the complaint brought by the U.S. government against Brazil at the WTO “court” (see section 5). Both actions were withdrawn after worldwide campaigns and media criticism, although the Brazil-U.S. dispute has now moved back from the WTO “court” to a bilateral forum.

Indeed, in bilateral and regional trade agreements, and in other non-WTO fora, the U.S. government – heavily lobbied by PhRMA – has pushed successfully for the introduction of “TRIPS-plus” levels of intellectual property protection (i.e., protection levels that exceed those contained in TRIPS). Examples include Vietnam, Jordan, Brazil, Thailand, and, most recently, Egypt. Although the U.S. does seem – following an Executive Order issued by President Clinton in May 2000 – to have stopped exerting overt pressure in the specific case of antiretrovirals in African countries,[27] the practice continues elsewhere. The Bush administration is pushing, for example, for the treaty governing the proposed Free Trade Area of the Americas to include patent protection of more than 20 years and to incorporate even tighter restrictions on compulsory licensing than under TRIPS.

What Next?

Except for the limited cases where safeguard provisions can successfully be utilized, the new trade rules will delay the introduction of generics into the market. The inevitable effect in many poor countries will be higher prices for essential medicines discovered after 1995. Products affected include many anti-HIV drugs currently on the market and any future improved drugs, from Pfizer or others, for HIV/AIDS, malaria, TB, and all of the other preventable and/or treatable diseases. Higher prices will restrict access to these important drugs and deepen the health divide between rich and poor countries.

Section 4

The Health Divide – Response of Pfizer and the industry

Summary

Despite owning three important drugs for infectious diseases – the antifungal Diflucan, the antibiotic Zithromax, and the antiretroviral Viracept – Pfizer, unlike a number of its competitors, has shown little flexibility on pricing and patent enforcement in poor countries. Where it has patents, it appears to adopt a broadly uniform pricing strategy and its policy is not to issue licenses to generic manufacturers. The result is that its drugs are often priced beyond the means of poor people and their governments. Pfizer's main response to the health crisis in the developing world has been to undertake limited donations (for example, Zithromax for one particular disease in a handful of countries). While Oxfam does welcome initiatives of this kind – and there are now many similar programs being undertaken by the leading pharmaceutical companies, partly in response to public pressure – in our opinion they are, taken together, no substitute for more systematic policies aimed at making medicines more widely available.

Section 3 showed that disease and high death rates in developing countries are inextricably (although not exclusively) linked to access to drugs, that access is intimately linked to prices, and that prices are in turn closely related to intellectual property rights, which in the future will increasingly be determined by the TRIPS agreement. Meanwhile, there is a dearth of R&D into new pharmaceuticals for diseases that are prevalent in developing countries.

This section is divided into two parts. The first looks at the three medicines in Pfizer's portfolio that are particularly relevant to developing countries. The second part evaluates some of the specific responses of Pfizer and the pharmaceutical industry in general to the rich/poor health divide, focusing in particular on price cuts and philanthropic programs, including Pfizer's significant Diflucan and Zithromax initiatives.

Access to Pfizer's Products

As discussed in section 2, three products sold by Pfizer are particularly relevant to diseases prevalent in developing countries: the antifungal Diflucan, the antiretroviral Viracept, and the antibiotic Zithromax.

Diflucan (fluconazole)

In 2000, global sales of Diflucan were just over US$1 billion (representing 4.5% of Pfizer's total human pharmaceuticals sales). Pfizer's approach to making this life-saving drug commercially available for the treatment of opportunistic infections associated with HIV/AIDS has come under intense criticism in a number of countries. In July 2000, Médecins Sans Frontières/Doctors Without

Borders (MSF) published a comparative price study of generic versions of fluconazole and Pfizer's branded product Diflucan. The findings (see Table 2) illustrated wide price differences.[28] Although cross-country comparisons are complicated by the influence on prices of exchange rate fluctuations, tariffs, sales taxes, inflation, and margins charged by distributors and retailers, generic equivalents are clearly substantially cheaper. While the Indian generics manufacturer Cipla sells fluconazole at $.64 apiece, for example, Diflucan is sold in Kenya at $10.50 per unit. This finding is consistent with other studies reporting up to a 90% price differential between brand name and generic drugs.[29] Other analyses of drug pricing generally confirm that it is the presence of patent protection that dictates the price of drugs, not local income and the ability to pay.[30] Patents are clearly the key to the affordability of drugs.

Table 2: Diflucan v. Fluconazole Price Comparisons

Manufacturer	Country of Distribution	Price per Unit (US$)
Biolab	Thailand	0.29
Cipla	India	0.64
Bussie	Guatemala (negotiated price)	3.00
Pfizer	Thailand	6.20
Vita	Spain	6.29
Pfizer	South Africa	8.25
Pfizer	Kenya	10.50
Pfizer	Spain	10.57
Pfizer	Guatemala (negotiated price)	11.84
Pfizer	USA	12.20
Pfizer	Guatemala (not negotiated)	27.60

Pfizer's main response to the health crisis in the developing world has been to undertake limited donations

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MSF's conclusions from its Diflucan/fluconazole study included two particularly significant points. First, where Pfizer has patents, it sells the medicine at broadly similar prices, irrespective of the ability to pay in different national markets. Second, were developing countries able to access generic equivalents, they would be able to reduce the price of fluconazole significantly. For example, if South Africa had been able to import fluconazole from Biolab, a Thai generics manufacturer, the cost of one year's maintenance treatment would have fallen from US$2,970 to US$104 per patient.

Further investigations by Oxfam have reached similar conclusions about the important role of generics in bringing down price. Although fluconazole is not patent-protected in Thailand, Pfizer's version – protected by a market exclusivity provision – was the only one on the market until 1998, when three Thai companies began production of generics. Pfizer then dropped its Diflucan price from US$7 per 200mg capsule to US$3.60. Having regained market share, helped by intensified marketing, Pfizer then raised its price back to US$6.20 per 200mg capsule, compared with the much lower generics prices (e.g., the Biolab price is US$0.29 for the same dosage).[31] In Brazil, Pfizer's branded version of fluconazole is called Zoltec. In July 2000 it was selling at a price almost double that of the cheapest available generic (see Table 3).

Table 3: Prices of Fluconazole Brands in Brazil[32]

Brand	Manufacturer	Price per pill (R$)
Zoltec ®	Pfizer	20.24
Flusan ®	Eurofarma	14.39
Pronazol ®	Diffucap-Chem	13.12
Lertus ®	Zodiac	11.48
Zoltatin ®	Biochimico	10.57
Fluconazol	Sanval	10.49
Triazol ®	Sanus	10.40

Although Pfizer has subsequently launched a fluconazole donations program in South Africa and is now proposing to extend this to a number of other countries (see page 24), the case of fluconazole illustrates well the general dilemmas for governments seeking an appropriate balance between the need for patent protection to encourage investment and innovation, and the desire to facilitate access to medicines for poor populations. The effect of Pfizer's policy of high prices and strong patent protection has been not only to limit poor people's access to Diflucan, but also, in countries where the product is patent protected, to deny access to generic equivalents until the patent expires.

Under TRIPS, generic producers will be unable to compete with patented products for at least twenty years from the date of patent filing (or typically 10-15 years from launch, assuming 5-10 years between patent filing and launch).[33] Industry spokespeople tend to argue the need for a roughly uniform

Viracept (nelfinavir)

pricing policy in order to prevent the parallel importation of cheaper medicines from low-price markets into higher-priced ones. The industry's critics argue that if the net outcome is to further limit poor people's access to life-saving medicines, it is incumbent upon the industry to exercise considerably more flexibility and social responsibility, and upon governments to assume a greater role. We look at these arguments in much more detail in section 6.

Viracept (nelfinavir)

Viracept is the best-selling drug in the protease inhibitor class of antiretrovirals. It works by disrupting the ability of HIV, the virus that causes AIDS, to replicate itself inside the human cell. Pfizer describes it as one "of the products that will drive the continuing success of the [newly-merged] company." It has great potential use in the treatment of HIV in poor countries.

The geographical distribution of Pfizer's many patent filings for nelfinavir include South Africa and the member states of the African Regional Industrial Property Organization (ARIPO), giving it patent protection in these countries until 2014. In South Africa, 4.7 million people are estimated to be HIV-positive and ARIPO members include countries with some of the highest incidence of HIV/AIDS in the world: Tanzania (1.3 million people), Mozambique (1.2 million), Kenya (2.1 million), and Uganda (1.5 million). The UN categorizes nine of ARIPO's fifteen member states as among the poorest countries in the world.

Nelfinavir is licensed to Roche in Europe and other countries outside North America, Japan, and Asia in exchange for a sales-based royalty. Because Pfizer maintains a financial stake in the sales of its patented drug, nelfinavir, Pfizer therefore benefits from whatever patent-protected decisions Roche has the power to make on its prices.

Roche has offered to make the drug available at concessionary prices in a number of developing countries under the UNAIDS-led Accelerating Access Initiative (see page 26). However, the price cuts offered have not been publicized and are reportedly relatively small. Roche is meanwhile fighting hard against pressure to lower nelfinavir's price in Brazil.

In 1996, Brazil introduced an AIDS program that aims to provide antiretrovirals free of charge to HIV/AIDS patients. This much-admired policy has been credited with halving the country's AIDS mortality rate and an 80% fall in its hospitalization rate.[34] The program currently uses twelve antiretroviral drugs. Of these, ten have never been patented in Brazil (where patents on pharmaceuticals were not introduced until 1996) and are therefore sourced cheaply through local generic production or importation. The two patented drugs are Merck's efavirenz and Roche's nelfinavir. Because of their relatively high prices, they together accounted for over a third of the Brazilian government's total AIDS drugs bill last year. Nelfinavir alone accounted for 28% (or US$85 million). Merck eventually agreed in March 2001 to cut the price of efavirenz by around 60%, but Roche has thus far resisted government pressure for substantial price cuts. In mid-May of the same year, the Brazilian government warned Roche that it intended to issue a compulsory license for local generic manufacture of the drug if an adequate price cut was not offered by July 2001.[35]

Zithromax (azithromycin)

Zithromax (azithromycin)

Azithromycin is an important antibiotic well-known for its efficacy in treating trachoma (one of the leading causes of preventable blindness in developing countries). In clinical and community trials in five developing countries, one dose of the medicine was found to be as effective against trachoma as the previously recommended six-week multidose tetracycline regimen. The crucial difference is that the single oral dose of azithromycin is much easier to use than the twice-daily and longer-term course of tetracycline.

Pfizer donates Zithromax for use against trachoma in a number of poor countries (see page 29). However, the medicine's effectiveness extends well beyond trachoma. It can be used to treat a whole range of infections, including pharyngitis, tonsillitis, and skin and ear infections, and it has become the most prescribed branded antibiotic in the U.S. Azithromycin is also a powerful agent against *Streptococcus pneumonia* and *Haemophilus influenzae*. These pathogens are the prime causes of respiratory tract infections, and in particular pneumonia, which is the number one killer of children worldwide.[36] Pfizer's donation program is for trachoma and not these other uses.[37]

Azithromycin's potential to treat pneumonia and other killer diseases in developing countries is one reason that MSF recommended in 1999 that it be added to the WHO's Essential Drugs List. This list is adapted for use by national health services and used as the backbone of many governments' medicines policies. Although azithromycin has been proven extremely safe and highly effective, especially for children, it is still not on the WHO list due to cost considerations (affordability is one of the criteria for a drug's inclusion on the list). For many developing countries, Zithromax is priced out of reach both of the government and most individuals. A study of East Africa by MSF[38] found the price to vary from US$2.70 per 250mg unit in Kenya to US$3.40 in Tanzania (i.e., roughly half the US$5.80 price for double that dosage in Norway). The annual per capita health expenditure is just US$17 in Kenya, compared with US$2,283 in Norway.[39]

Life-saving medicines may be priced out of the reach of poor people, yet generic competition, which could bring down the price substantially, is not permitted in countries that grant patents during the period of patent protection

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Company Initiatives – Philanthropy and Self-interest

The Industry's Reaction to the Growing Public Pressure

Pfizer's apparently roughly uniform international pricing policies for Diflucan and Zithromax are good specific examples of the general problem. Life-saving medicines may be priced out of the reach of poor people, yet generic competition, which could bring down the price substantially, is not permitted in countries that grant patents (i.e., under TRIPS, eventually all WTO members) during the period of patent protection.

Criticism of the industry therefore continues to mount amid concerns that TRIPS will exacerbate the health divide. Pharmaceutical companies obviously cannot be expected to bear the entire burden of health care in the developing world – they are not charities, and drugs are in any case not the whole answer. However, the industry does have the resources – including product patents, low-cost production processes, and R&D expertise – to make a much greater impact than it does, particularly because it is consistently among the most profitable of all industries. The low priority given to public health considerations in the developing world by pharmaceutical companies has drawn increasingly vocal criticism.

The Wall Street Journal recently described the industry as "reeling from an unprecedented wave of public scorn,"[40] and *The Economist* asked, "How did the industry get itself into such a mess?"[41]

As the public health crisis unfolds, both the public and investors are questioning the performance of companies that fail to address these issues in developing country markets. The Internet is playing a huge role in raising awareness of global health disparities and mobilizing pressure for change. Companies that are slow to react, or whose price cuts and philanthropic efforts appear inadequate in relation to need and to the resources available to them, risk poor public relations, shareholder actions, and – more importantly for them – sustained damage to their share prices. This can happen in various ways. Shifts in consumers' purchasing patterns might be particularly relevant to companies such as Pfizer and GSK, with their sizeable consumer health businesses. More subtly, a poor public image is likely to have adverse effects on staff morale and recruitment. Probably most threateningly, lobbying has its limits in the face of public opposition, and the industry risks losing the invaluable support of governments and legislators in

The Wall Street Journal recently described the industry as

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"How did the industry get itself into such a mess?"

Public-Private Partnerships

industrialized countries if public opinion continues to move against it.

The objective of company boards is not solely to maximize profit every year but to maximize shareholder value. The growing risks described in the previous paragraph have meant that shareholder value and pro-poor policies have in recent years become more closely aligned. Responding to the mounting public criticism of industry policies, many companies have stepped up their price cuts and philanthropic activities by entering into non-commercial, well-publicized initiatives, usually in conjunction with public bodies. These public-private partnerships (PPPs) generally involve at cost or free drug donations or deep price cuts in specific disease areas and countries. Recent moves in the HIV/AIDS area include:

- In May 2000, five companies, including Pfizer's nelfinavir licensee Roche, joined the UNAIDS-led Accelerating Access to HIV/AIDS Care and Treatment Initiative (AAI) aimed at HIV prevention and treatment in some developing countries. This included the offer to sell to the governments of these countries, subject to certain conditions, a range of anti-HIV drugs at prices up to 90% lower than in industrialized countries. Pfizer has not joined AAI, saying that it prefers to remain independent so as to be more nimble and dynamic.[42]
- Three of these five companies have recently announced that they would go further than originally envisaged. Merck and Bristol-Myers Squibb will cut prices again (this time to levels at that they claim they would make no profit). In its report,

"Facing the Challenge," GSK extends price offers on additional HIV/AIDS and anti-malarial medicines to a wider range of countries and customer groups.[43] In addition, it commits to undertaking a pilot study to assess the impact of price reductions for anti-infectives, deworming agents, and anti-diarrheals in poor countries.

Bristol-Myers Squibb, makers of ddI (Videx brand didanosine) and d4T (Zerit brand stavudine), has promised $100 million to its "Secure the Future" program, which involves setting up HIV prevention, treatment, and research programs in a number of African countries.

In addition, Bristol-Myers Squibb, Boehringer Ingelheim, GSK, Merck & Co., Hoffman-LaRoche, and Abbott Laboratories, among others, have launched other philanthropic initiatives.[44]

Price cuts and philanthropic programs and PPPs generally can – if well-designed – make an important contribution in particular areas, but they are inadequate in isolation and cannot be regarded as alternatives to more systematic policies to promote access to affordable medicines. They often bear little relation to the scale of the problem and leave developing countries too reliant on chance and the goodwill of companies. They are piecemeal, reversible, and frequently conditional. Thus, while Pfizer has recently announced a new initiative to extend its Diflucan donation program to more countries for an unlimited period, its original program was limited to particular patients in one country for a finite period, and even the expanded program is still piece-

The growing risks have meant that shareholder value and pro-poor policies have in recent years become more closely aligned

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Unlike a number of its competitors, Pfizer has shown little

meal and an insufficient alternative to systematic policies that promote access.

Moreover, even deeply cut prices are often beyond the reach of poor countries and their governments (at the time of writing, only seven countries have signed up to the Accelerating Access Initiative, and the number of patients expected to be treated is tiny in comparison to the incidence of HIV). Offers of hefty price cuts provide no guarantee that the best attainable prices are achieved, as evidenced by the recent further price cuts by Merck and Bristol-Myers Squibb on their HIV drugs and by the offers by Cipla and other generics companies to undercut the prices offered under the Accelerating Access Initiative.[45] Even claims by patent holders that products are being sold "at cost" are debatable as much depends on how overheads are allocated and therefore how "cost" is defined.

Pfizer has shown little flexibility in its policies on patents or prices

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Pfizer's Donation Programs

Unlike a number of its competitors, Pfizer has shown little flexibility in its policies on patents or prices. For example, one way Pfizer could facilitate broader access to its life-saving medicines would be to issue voluntary licenses in poor countries, thereby enabling health officials to arrange for the production or importation of affordable generic equivalents, while protecting Pfizer's intellectual property position elsewhere. Indeed, in December 2000, Cipla wrote to Pfizer's head of patents requesting just such licenses for the production of a generic version of fluconazole in return for royalty payments of up to 5% of sales. Pfizer has yet to respond to Cipla, but it has told Oxfam that it is not its policy to issue such voluntary licenses.

Instead, the company's response to the health divide has been to favor philanthropy in the form of patient-assistance programs for people in the U.S. who are uninsured and cannot afford critical medicines, and through limited donations programs in developing countries.

Pfizer initiated a fluconazole donations program in South Africa in March 2000. The program was criticized by international and national-based groups such as South Africa's Treatment Action Campaign (TAC), ACT UP Philadelphia and Paris, and MSF, for the fact that it was limited to South Africa and initially intended to be limited to people suffering from cryptococcal meningitis, only one of the two common opportunistic infections associated with HIV/AIDS. In June 2000, ACT UP and TAC demanded that the program be extended to those suffering from systemic thrush—the more common of the two infections. A short time later, this group was also made eligible. Although welcomed by the

South African government, this program has been criticized by leading groups for being *ad hoc* and limited, for burdening the health system with significant administrative costs, and for being a preemptive move to prevent generic competition from exercising a downward influence on prices. On June 6, 2001, Pfizer announced that it would extend the offer of free Diflucan to HIV/AIDS patients in the fifty least-developed countries where HIV/AIDS is most prevalent. The company argues that its philanthropic programs are not the result of international campaigning and media criticism.[46] However, Oxfam believes that this is open to interpretation in view of the chronology of events in the history of the Diflucan program. Although it could be argued that Pfizer would have undertaken this initiative anyway, in Oxfam's opinion it was made more likely by the pressure on the industry to reduce prices throughout 2001.

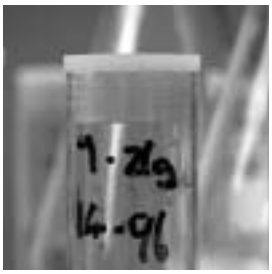
Turning to azithromycin, the International Trachoma Initiative is a public-private partnership formed in 1998. Working with international agencies and with government and non-governmental organizations to combat trachoma in developing countries, Pfizer now has programs in Morocco, Tanzania, Vietnam, Sudan, Ghana, and Mali.[47] The partnership, between the Edna McConnell Clark Foundation and Pfizer, treats the disease by focusing on simple surgery, the provision of antibiotics, face washing and improved access to clean water, better sanitation, and increased health education.

A third large-scale project is the announcement on June 11, 2001, that Pfizer will fund Africa's first major treatment and training center for HIV/AIDS, based in the Ugandan capital, Kampala.

Pfizer's corporate philanthropy also extends beyond the fluconazole and azithromycin donations programs and this new center. The Pfizer Foundation is an independent charitable foundation established by Pfizer in 1953. The foundation's mission is "to promote access to quality health care and education, to nurture innovation and to support the community involvement of Pfizer people." The company's other philanthropic activities focus on science and math education, health promotion, and community development. Pfizer has informed Oxfam that its Health Education Programs have reached 2.3 million people.[48]

While Oxfam welcomes well-run donations programs, and Pfizer's programs are certainly of value to their recipients, in Oxfam's opinion Pfizer is in a position to undertake much more comprehensive efforts in improving access to essential medicines – both through further expansion of its donations programs and even more importantly through revision of its patent and pricing policies.

Pfizer should take a more prominent leadership role in demonstrating sensitivity to the current global debate on corporate social responsibility. Companies are increasingly being called into account – not primarily for how generous their philanthropic donations are, but for the impact of their core business practices on human development across the globe. As has been shown in the section on fluconazole, Pfizer's policy of high prices and aggressive enforcement of its patents are key factors that limit access to life-saving medicines for poor people. To align its business more closely with the health needs of poor people, Pfizer needs to exercise greater flexibility in its patent and pricing policies.



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Companies are increasingly being called into account for the impact of their core business practices on human development across the globe

Section 5

Power and Pressure

Pfizer's Lobbying

Summary

Pfizer has lobbied vigorously and successfully in support of its commercial interests, notwithstanding the public health implications. Its chief executive is the chairman of PhRMA, the most powerful pharmaceutical industry lobby in the U.S. It has close links with government and its personnel occupy a number of important policy-shaping roles. It was a driving force in putting intellectual property on the trade agenda and was instrumental in the eventual adoption of TRIPS. It has played a leading role in encouraging the U.S. administration to use bilateral negotiations and unilateral economic sanctions – including making suggestions as to who should be placed on the U.S. Government's 301 Priority Watch List – against countries that it believes offer inadequate patent protection.

Influencing the Policy Makers

Pfizer has a long track record of actively lobbying both in the U.S. and globally to further its commercial interests on such issues as domestic health care reform and international patent protection. It is the most visible advocate for the industry with the U.S. government, especially on intellectual property rights and TRIPS. Pfizer has also made substantial political donations. During the 2000 U.S. election cycle, the company made the second-highest monetary contribution, donating US$2.3 million, 86% of which went to the Republican Party.[49]

Pfizer conducts its lobbying through its own staff as well as through external political lobbyists. It has regularly been one of the top five spenders on lobbying. In 1999 alone, Pfizer spent US$3.8 million and Warner-Lambert spent US$2.2 million on external lobbyists in the U.S.[50] A number of the lobbyists employed by the company have held influential positions in previous administrations.

Pfizer's chairman and CEO, Henry McKinnell, recently took over the chairmanship of PhRMA. He is also a member of the Board of Directors of the Business Roundtable (BRT) and vice-chairman of the BRT's Corporate Governance Task Force.[51] The CEO of Pfizer U.K. is the vice-president of the Association of the British Pharmaceutical Industry (ABPI). Pfizer is a member of a number of powerful U.S. industry lobbies. These include the Business Roundtable, the TransAtlantic Business Dialogue, the U.S. Chamber of Commerce, the International Chamber of Commerce, and the Business and Industry Advisory Committee (BIAC), as well as bilateral business councils such as the U.S.- Brazil Council. Senior managers

In 1999 alone, Pfizer spent **US$3.8 million**

and Warner-Lambert spent **US$2.2 million**

on external lobbyists in the U.S.

chair the European Union and intellectual property committees of the U.S. Council for International Business (USCIB).

Pfizer has also sat on a number of governmental advisory committees over the years, including the US President's Advisory Committee on Trade and Policy Negotiations (see below). In addition, it has recently been appointed to the Commission on Intellectual Property Rights established by the U.K. government to investigate how intellectual property rules might develop in the future to take into account the interests of developing countries and poor people.

Pfizer Europe was part of the EuropaBio industry lobby group that pushed through the controversial Directive on the Legal Protection of Biotechnological Inventions, or the Life Patents Directive. This directive, passed in May 1998 by the European Parliament, allows companies to patent genes, cells, plants, animals, human body parts, and genetically modified or cloned human embryos.[52] At the global level, the company is also part of the International Bioindustry Forum, which protects the same interests at the UN policy-making level.[53]

Pfizer and the Origin of TRIPS

The negotiations on the Uruguay Round of the General Agreement on Tariffs and Trade (GATT), which began in September 1986, gave Pfizer the opportunity to lobby for its preferred global intellectual property regime. It was a driving force in putting intellectual property on the trade agenda and instrumental in the eventual adoption of TRIPS. The commercial impact has clearly been fully assessed by the company. In Oxfam's opinion, it is equally obvious that the social or public health implications of the agreement were not Pfizer's priority consideration.

Pfizer had been frustrated at the system administered by the UN-based World Intellectual Property Organization (WIPO). Expressing this, Pfizer's general counsel at the time stated: "As a UN organization, WIPO works by majority, and simply put, there were more of them than us. Our experience with WIPO was the last straw in our attempt to operate by persuasion."[54] In other words, Pfizer believed that the developing countries in WIPO opposed changing the current regime as set up under the existing treaties and WIPO, and that the U.S. alone could not bring about the change the company wanted. As a response to this, Pfizer succeeded in adding intellectual property protection onto the GATT agenda for the first time. (See table 4 on the next page.)

Table 4: Pfizer and Intellectual Property

Organizational Arena	Pfizer's Role
World Intellectual Property Organization (WIPO)	**1979-1986** Initially, Pfizer hoped to bring tighter intellectual property standards to WIPO. However, Pfizer subsequently expressed its frustration with the organization, deeming WIPO "inadequate to the task" and stating that "as part of the UN system, WIPO identifies with the special interests of the very governments in the developing world who abet the theft of intellectual property."[a] Further displaying this frustration, Pfizer's General Counsel at the time stated: "As a UN organization, WIPO works by majority, and simply put, there were more of them than us. Our experience with WIPO was the last straw in our attempt to operate by persuasion."[b] [a]Sylvia Ostry, Governments and Corporations in a Shrinking World: Trade and Innovation Policies in the United States, Europe, and Japan (New York: Council on Foreign Relations, 1990) , 24. [b]As quoted in this report, page 31.
General Agreement on Tariffs and Trade (GATT)/Uruguay Rounds	**1986-1994** Having abandoned WIPO, Pfizer pushed the debate into the GATT arena by way of its Chairman Edmund Pratt's influential positions as the chairman of the President's Advisory Committee for Trade Policy and Negotiation (ACTPN), a key member of President Ronald Reagan's Business Advisory Committee on International Trade, and one of the chief architects of the Intellectual Property Committee (IPC). In mounting this offensive, Pratt noted of industry, "Our combined strength enabled us to establish a global private sector government network that laid the groundwork for what became TRIPs."[a] In addition, Pfizer hoped that this move would result in greater security and compliance and believed that "enforcement mechanism[s] and dispute settlement could be instituted through the GATT"[b] [a] Edmund T. Pratt, Jr., "Pfizer Forum: Intellectual Property Rights and International Trade", *The Economist*, May 27, 1995, p. 26. [b]Sylvia Ostry, Governments and Corporations in a Shrinking World: Trade and Innovation Policies in the United States, Europe, and Japan (New York: Council on Foreign Relations, 1990) , 24.
World Trade Organization (WTO)/Trade Related Intellectual Property (TRIPs)	**1995-Present** Before 1995, Pfizer successfully used the Uruguay forum to push for the adoption of the TRIPs agreement in what became the WTO. Since then, Pfizer has attempted to use the more stringent protocols and enforcement mechanisms set forth by TRIPs and the WTO's requirement that all of its members adhere to "the whole package [of intellectual property rights] rather than being able to select specific agreements for signature," to further strengthen international compliance and to push for greater sanctions in the case of patent violations.[a] As Jacques Gorlin, director of the Intellectual Property Committee, stated, "there are penalties for piracy in the WTO-TRIPs rules . . . [which are] significant enough for developing countries to take notice that they can no longer simply disregard international complaints."[b] Pfizer continues to push for stronger patent protections, or "Trips -plus." [a]As quoted in this report, page 33. [b]Jacques Gorlin, director of the Intellectual Property Committee and president of the Gorlin Group, as quoted in the Pfizer Journal Global Edition, Vol. 1, Num. 2, 2000.

Pfizer and the Origin of TRIPS

Before the Uruguay Round, the raison d'être of GATT was to move toward the reduction of trade barriers through the removal of tariffs and subsidies. With this round, the concept of TRIPS and "trade-related" regimes emerged as a new component of the agreement. Intellectual property rights became governed by international trade rules, and governments were obliged to align their domestic legislation and policies accordingly. Critically, the establishment of the WTO provided a more enforceable and tougher sanction mechanism for violations of those rules. Finally, the agreements negotiated at the Uruguay Round were presented as a single undertaking – i.e., countries had to accept the whole package rather than being able to select specific agreements for signature.

Pfizer was in a good position to lobby the U.S. administration on these issues. In 1979, Edmund Pratt, then Pfizer's chairman, had been appointed to the president's Advisory Committee on Trade and Policy Negotiations (ACTPN). Two years later, he became chair of this committee and remained in this role until 1986. The advisory committee system was established by the U.S. Congress in 1974 to facilitate the provision of advice from the U.S. business sector in three areas: U.S. negotiating objectives and bargaining positions before entering into trade agreements; the operation of any trade agreement once entered into; and other matters arising in connection with the development, implementation, and administration of U.S. trade policy.[55] Pratt subsequently became a special advisor to the United States Trade Representative (USTR) when he retired from Pfizer with the title of Chairman Emeritus. Other Pfizer executives also held influential positions: Lou Clemente, Pfizer's general counsel, headed the Intellectual Property Committee of the USCIB, and Gerald Laubach, president of Pfizer Inc., was on the Council on Competitiveness and on the board of the Pharmaceutical Manufacturers Association (the precursor to PhRMA)[56]. Pfizer also ensured that its views were put to some of the major policy think tanks in the U.S., including the Heritage Foundation, the American Enterprise Institute, the Hoover Institution, and the Brookings Institution.[57]

Together with IBM chairperson John Opel (who chaired the Intellectual Property Taskforce of the ACTPN), Mr. Pratt developed proposals to include intellectual property on the agenda of the Uruguay Round, and these were circulated to the U.S. president, the U.S. Trade Representative, and other trade officials. Providing some solutions to U.S. fears of loss of competitiveness in the global market, the proposals outlined a course of action to advance the U.S. government's desirefor gaining leverage. They suggested a long-term goal of incorporating intellectual property within the GATT framework and an interim strategy of placing bilateral and unilateral pressure on countries lacking adequate intellectual property protection.[58]

These proposals were accepted by the U.S. government. If, however, the long-term goal of their inclusion in GATT was to be achieved, other industrialized countries would have to be lobbied very hard. Neither the Europeans nor the Japanese were enthusiastic. Heeding the advice of the USTR, Pratt and Opel mobilized eleven other multinational companies[59]to form the Intellectual Property Committee (IPC) in March 1986. The aims of the IPC were to garner government support for its objectives through partnership with business associations in these localities. The IPC successfully formed an alliance with the European Union of Industrial and Employers' Confederations (UNICE) and the Keidanren, the Japanese industry coalition. Together, they released

their 'Basic Framework,' a 100-page document[60] that outlined the fundamental provisions of patent protection that was to become the basis of TRIPS.

Pfizer took the lead in aggressively pushing for TRIPS throughout the negotiations, threatening to oppose ratification of any Uruguay Round agreement by the U.S. Congress if it was not to its liking. Though negotiations on TRIPS were tough, the agreement came into force in 1995 with the other agreements of the Uruguay Round, along with the establishment of the WTO. Mr. Pratt has been quoted as saying: "Our [the industry's] combined strength enabled us to establish a global private sector government network that laid the groundwork for what became TRIPS."[61]

Pfizer has played a leading role in pressuring the U.S. administration to use bilateral negotiations and unilateral economic sanctions against countries that it believes have weak patent protection

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Despite this success, the industry continues to expand and deepen its quest for patent protection. In his testimony to the U.S. House of Representatives' Ways and Means Committee in March 1996 as representative of the IPC, Peter Richardson, senior assistant general counsel for Pfizer, voiced the industry's objections to the transition periods provided to developing countries: "long TRIPS transition periods are forcing us to look outside the WTO for instruments to gain IP protection in the developing countries."[62] This contrasts with the recognition by a number of international leaders that many developing countries faced serious implementation problems in meeting the agreed TRIPS transition timetable.

Richardson recommended that the U.S. use a number of mechanisms to ensure that TRIPS-compliant legislation was enacted quickly. (This included pushing the Singapore WTO Ministerial Meeting to agree to an acceleration in the transition provisions and using the regional free trade initiatives like the FTAA as vehicles for implementation of higher levels of patent protection).[63] Lobbying has also been conducted at the national level in various developing countries. In Brazil, for example, Pfizer participated in the aggressive lobbying activities of Interfarma, a coalition of multinational pharmaceutical companies that was formed for the express purpose of influencing the early passage of the Industrial Property Law. This law granted patent protection on pharmaceuticals and took effect in 1997, eight years earlier than required under TRIPS.

A number of countries have felt the heavy hand of

Section 301

Pfizer, Section 301 and TRIPS enforcement

As a parallel strategy, Pfizer has played a leading role in pressuring the U.S. administration to use bilateral negotiations and unilateral economic sanctions against countries that it believes have weak patent protection. It has significantly influenced the development and implementation of the Section 301 mechanism.

In the early 1980s, Pfizer worked with the USTR and the Pharmaceutical Manufacturers Association to develop a position paper that formed the basis of a presidential statement on the importance of intellectual property to the U.S.[64] This paper contributed to change in the U.S. international trade law in 1984. New legislation, known as Section 301 of the Trade and Tariff Act, allowed the U.S. government to take retaliatory action against countries failing to give adequate protection to intellectual property. Additionally, Section 501 of the act authorized the president to evaluate the degree of the intellectual property protection afforded by a country when considering granting tariff preferences under the Generalized System of Preferences.

In 1998, an Omnibus Trade and Competitiveness Act strengthened the implementation of Section 301 by introducing the 'Special 301' provision. This required the USTR to identify countries that denied adequate intellectual property protection to U.S. firms and, depending on the perceived severity, to warn those countries to shape up, to present them with a plan for progress, or to apply trade sanctions.[65]

The 301 process depends upon surveillance. U.S. companies provide the information directly to the USTR or through their trade associations. PhRMA, for example, files a report on an annual as well as special basis to the USTR. PhRMA recommends how countries should be categorized and what action should be taken to punish those it thinks have failed. In its dual capacity as a lead PhRMA member, as well as on its own behalf, Pfizer has pressured U.S. officials to exercise its leverage through these mechanisms. The latest PhRMA recommendations to the USTR list thirty-seven countries to be targeted. PhRMA's strategy is to highlight the alleged financial losses to the U.S. pharmaceutical industry from what they perceive to be inadequate patent protection. In lobbying for sanctions, PhRMA adopts a very narrow interpretation of TRIPS, which leaves no space for developing countries to define their policies according to public health needs. The phraseology of the USTR's report on actions to be taken under Section 301 is remarkably similar to PhRMA's recommendations.

A number of countries have felt the heavy hand of Section 301 and other unilateral retaliatory measures from the U.S., including Thailand, South Africa, and Brazil. Brazil in particular appears to have come under aggressive scrutiny (see box 1).

BOX 1:

Pfizer in Brazil

Brazil, a middle-income country, is seen as a lucrative market for the pharmaceutical industry. The Brazilian market, however, is greatly polarized with the majority of the population too poor to purchase needed medicines. Some 60 million Brazilians (about one third of the population) live in poverty and account for just 16% of total drug consumption. Drug prices remain high, reflecting the purchasing power of a minority of the population. Prices have come under some scrutiny by the Brazilian government. The Consumer Defense Code and legislation on economic crimes empower the Ministry of Justice to investigate abusive pricing by manufacturers. A Parliamentary Commission of Inquiry was set up in early 2000 to conduct investigations using these legal instruments.

Pfizer is one of the top ten pharmaceutical manufacturers in Brazil and has been present in the country for nearly fifty years. Its most successful products in this market are Zithromax, Feldene, Zoltec, and Viagra. To the majority of Brazilians, its medicines are unaffordable. Indeed, it has been under investigation by the Ministry of Justice for price increases of eight different drugs.[66]

Pfizer Sales in Brazil[67]

Selected Drugs

		1999		1998	
Drug	**Generic name**	**Units Sold**	**Value in US$**	**Units Sold**	**Value in US$**
Zithromax®	Azithromycin	609, 000	11,380,000	1,023,000	24,387,000
Zoltec®	Fluconazole	345,000	5,105,000	667,000	12,650,000
Viagra®	Sildenafil	1,162,000	29,806,000	603,000	19,576,000
Feldene®	Piroxicam	2,862,000	15,858,000	3,503,000	26,942,000

Pfizer recognizes Brazil as a market of significance. This is reflected in the interest it has taken in national developments that affect the pharmaceutical industry. In particular, Pfizer has been involved in lobbying surrounding the introduction of TRIPS-compliant intellectual property laws in Brazil. Pfizer is an active member of Interfarma, a coalition of multinational pharmaceutical companies, formed for the express purpose of influencing the passage in Brazil of the 1996 Industrial Property Bill. This bill included “TRIPS plus” clauses such as a ban on parallel importing, and the allowing of late patenting (which permits patent approval even if filed later than one year from the original date of filing). Methods used by Interfarma to lobby those involved in the drafting process included expenses-paid overseas travel.[68] Pfizer also was, and still is, a member of ABIFARMA, which is the Brazilian equivalent of the U.S. PhRMA.

These lobbying activities mirror a history of U.S. pressure upon Brazil on intellectual property. In 1987, PhRMA complained to the USTR of Brazil's lack of process and patent protection for pharmaceutical products as an unreasonable practice that burdens or restricts U.S. commerce. The following year, the Reagan administration imposed 100%

tariffs on US$39 million worth of Brazilian imports. These sanctions remained until the Brazilian government amended its patent laws in 1990.[69]

Most recently, following PhRMA recommendations, Brazil was targeted again by the U.S. administration through the initiation of a WTO dispute against Brazil claiming that the latter's legislation was not TRIPS-compliant. In the heat of political and public pressure, however, the U.S. finally withdrew its challenge on June 25, 2001, stating that the differences would be resolved through the U.S.-Brazil bilateral consultative mechanism.

Conclusion

Pfizer continues to lobby actively for yet higher levels of patent protection throughout the world despite civil society criticisms about the impact of TRIPS on access to affordable life-saving medicines. Its former chairperson, Edmund Pratt, has said: "Pfizer will continue to do all it can to carry the intellectual property rights banner forward, helping to write new chapters in this saga to protect products of the mind."[70]

To the majority of Brazilians, Pfizer's medicines are unaffordable

JENNY MATHEWS/OXFAM

Section 6

Time for action

Summary

Oxfam fully accepts that patents can be an important incentive for R&D, but we believe the "one-size-fits-all" TRIPS system has huge failings and must be reformed. Although the pharmaceutical industry continues to fight hard in defense of lengthy and globally uniform patent protection, we believe that many of the arguments it routinely uses in support of its case are flawed. Box 2 on pages 40-41 explains precisely why. We urge the individuals at the helms of the leading pharmaceutical companies to take much more seriously the responsibility bestowed upon them by the fact that they have it in their power to save many thousands of lives at little or no cost to themselves or their companies. With goodwill on all sides, substantial progress is possible this year.

Fundamental Reforms are Needed

Our specific recommendations to Pfizer in section 7 need to be set in the context of reform of the regulatory and commercial environment within which the big pharmaceutical companies must operate. Governments and multilateral institutions should supplement these reforms by providing financial resources to allow wider access to life-saving drugs and helping to determine and fund an R&D agenda into diseases that disproportionately affect the poor. Such a systematic approach could eliminate the current case-by-case battles over particular drugs in particular markets and lift developing countries' over-reliance on potentially reversible donations and price reductions from the pharmaceutical industry.

Oxfam believes patents play an important role in rewarding innovation and encouraging investment into R&D. However, we believe that the "one-size-fits-all" TRIPS system has huge failings. What is needed is a patent regime that combines incentives for R&D with improved access to affordable life-saving medicines.

Substantial progress is possible, although far from certain, this year. The WTO's Council for TRIPS is, under the Uruguay Round final Act signed in 1994, due to conduct a review of the agreement. At the urging of African countries, the Council for TRIPS held a special health day on June 20, 2001, to discuss intellectual property and access to drugs, and TRIPS seems certain

What is needed is a patent regime that combines incentives for R&D with improved access to affordable life-saving medicines

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to be a key subject for discussion at the WTO ministerial meeting in Qatar in November and in any future trade round. In addition, the issue of access to drugs is under urgent consideration elsewhere, including in many parts of the UN, among the G8 countries, and in the U.K. government's Commission on Intellectual Property Rights.

Oxfam calls for these bodies to support modification and clarification of TRIPS to include:

- greater flexibility in the scope and duration of patents in developing countries to give greater weight to public health considerations.
- easing restrictions on compulsory licensing and simplifying the procedural requirements. As a minimum, TRIPS should be modified to confirm that overseas companies can be used as licensees; specify any royalty rate that must be paid; and permit Brazil-type local working requirements.
- an extension of the current transition periods for TRIPS compliance.

Such changes would be a critical step in the right direction, but would not be enough. Access to patented medicines would still be restricted by high prices (however short the period of patent protection). Even generic prices are frequently too high to be affordable in poor countries. Furthermore, there would still be many diseases for which effective drugs do not yet exist. Oxfam the refore also calls for:

- systematic "tiered pricing" (or "differential pricing") of patent-protected drugs, with prices based on transparent and objective criteria that reflect health and development needs and purchasing power in different countries.
- measures to address the legitimate concerns of the industry about leakage of generics or low-price patent-protected drugs to high-price industrialized markets[71] and about prices in developing countries being used as a "benchmark" in other countries.
- substantial government contributions to the UN fund (to be launched at the G8 Meeting in Genoa in July 2001) to help poor countries to improve access to health services, including medicines. This fund may act as an additional incentive for R&D into neglected areas by boosting the potential market.
- an additional dedicated global research fund aimed in particular at new vaccines and treatments for HIV, malaria, TB, sleeping sickness, etc., should supplement the abovementioned fund. Such a fund would be a far more effective way of encouraging pro-poor R&D than relying on patent protection, which does nothing to address the issue of purchasing power.

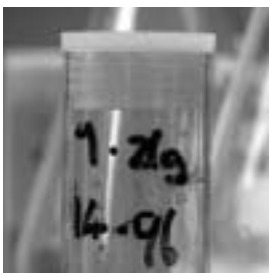
Objections from Pfizer and the Pharmaceuticals Industry

The industry – with very few exceptions – continues to aggressively defend the patent protections it has achieved and continues to flex its lobbying muscle to extend these yet further, as exemplified by this quotation from PhRMA's 2000/1 annual report:

"A PhRMA priority this year is to enhance, if possible, the Trade-Related Intellectual Property Agreement (TRIPS) in the next round of World Trade Organisation (WTO) negotiations, but at a minimum to preserve current levels of protection provided by TRIPS."

For a detailed rebuttal of the arguments most commonly used by the industry against proposals for reform of TRIPS, see "Implausible Denial," an Oxfam policy paper published in April 2001.[72] Box 2 on pages 40-41 summarizes the main industry arguments and Oxfam's response to them.

The industry continues to aggressively defend the patent protections it has achieved and continues to flex its lobbying muscle to extend these yet further



MARK BUSHNELL

BOX 2:

Why the Drug Giants' Arguments on Patents Don't Stack Up

Argument 1: Patents are not a significant factor restricting access to medicines, as less than 5% of the drugs on the WHO essential drugs list are patent-protected.
Oxfam's opinion: This argument entirely misses the point that affordability is an explicit criterion for a drug's inclusion on the WHO list in the first place, which is why most antiretrovirals (other than for mother-to-child transmission) do not appear despite the global AIDS crisis.

Argument 2: A global market requires a uniform patent system, and without strong global patent protection the industry would lack incentives for undertaking R&D into major diseases.
Oxfam's opinion: We fully accept that patents can be an important incentive for R&D, but a "one-size-fits-all" patent system is unnecessary and undesirable. Only industrialized countries have the capacity to absorb the high prices (and therefore generate the substantial profits) that patents allow. In developing countries, where purchasing power is much more limited, applying stringent patent protection will not generate substantially more revenues or relevant R&D, but will limit poor people's access to medicines.

Argument 3: Differing patent periods or substantial price cuts in poor countries would result in rich countries' pharmaceutical markets being flooded with cheap generics or parallel imports, or with other downward pressures on prices, seriously undermining the industry's profitability.[71]
Oxfam's opinion: The risk of low-price generics or parallel imports of patented products leaking from developing to developed countries, or of consumers in rich countries using low prices elsewhere as a benchmark, is overstated and has in practice proved manageable (as the consistently high prices in the U.S. market demonstrate). It would be perfectly possible to have a differentiated patent regime and/or pricing policies tailored to the differing health and economic circumstances of individual countries.

Argument 4: Strong patent protection will not damage public health in developing countries if it is accompanied by public-private partnerships (PPPs) providing heavily discounted and/or donated drugs, and if the industry develops "tiered pricing" policies.
Oxfam's opinion: PPPs may be part of the solution, but are inadequate in isolation. They are ad hoc and reversible, frequently conditional, and provide no guarantee that the best attainable prices are achieved.

Argument 5: It takes US$500 million to bring a new drug to the market, and a twenty-year patent term is justified by the cost and risk associated with R&D into new drugs.
Oxfam's opinion: The industry is not as risky – and R&D not as costly – as often claimed. The industry's figure of US$500 million per new drug is misleading and the significant contribution of public funding to the discovery process is often glossed over. In addition, Oxfam questions whether a full twenty years of patent protection is necessary, even in rich markets, especially given the significant decline in average drug development and registration times from which the industry
has benefited in recent years. Because of "discounting," R&D investment decisions depend disproportionately on projected revenues in the early years after launch. Patents are important, but it is not very important for patents to be long, and not at all important for patents to be long everywhere.

Argument 6: Without effective patent protection there would be no R&D into 'Third

World' diseases.

Oxfam's opinion: Although there is chronic under-resourcing of R&D into such diseases, strong patent protection will not materially increase either the market potential in these disease areas or the incentive for R&D. There are much more effective ways of ensuring the necessary R&D such as the global research fund proposed by Oxfam. Meanwhile, strong patent protection in rich countries is enough incentive for R&D into diseases common to rich and poor countries.

Argument 7: Companies, like individuals, have the right to protect their property – including intellectual property – against theft, which is why they are seeking protection through the WTO.

Oxfam's opinion: Governments have to balance competing rights. Attempts to defend the right to health care by flexible patent enforcement are under threat by pressures from companies even when such flexibility is apparently consistent with TRIPS. Companies should respect the spirit and letter of the legal limitations on their patent rights and should take a broad view when deciding how vigorously to enforce their patents. Where they fail to do so, and insist on a rigid approach to patent enforcement at the expense of poor people's health, they risk public opprobrium and real and lasting damage to their share prices.

Argument 8: Generics manufacturers make sub-standard products and are driven by their own profit motives.

Oxfam's opinion: Large generics companies that export to developed nations have to pass regular inspection by regulating authorities, such as the Food and Drug Administration in the case of the U.S. Generics companies do indeed usually seek to make profits, but it is still the case that their products are sold at cheaper prices than branded products. From a development perspective, this provides a significant health benefit to poor people by improving access to essential medicines.

It's Time for Action

Although the details were specific to South Africa, the outcome of the recent legal case in that country is likely to prove precedent-setting in the encouragement it gives other developing-country governments to make use of the TRIPS safeguards. Following that case, the pressure for progress in addressing the health divide is immense. Unless the industry recognizes this, we believe that it risks being overtaken by events, losing not only more public support but also – far more damagingly – the support it still enjoys from the governments of most industrialized countries.

Our specific recommendations to Pfizer are listed in the next section. As a general point, however, we urge the individuals at the helms of the leading pharmaceutical companies to take much more seriously the responsibility bestowed upon them by the fact that they have it in their power to save many thousands of lives at little or no cost to themselves or their companies. As a recent editorial in the respected medical journal *The Lancet* put it:

"The time has come for the pharmaceutical industry and the governments who represent them in trade disputes to acknowledge that the world is facing an extraordinary challenge."[73]

And as a recent article in *Foreign Affairs* argued:

"The global economic order will not work for the United States, Europe, and Japan unless it also works for India, Brazil, and South Africa. A system that seems rigged to aid the wealthiest and most competitive countries will be undermined by the poorest and least competitive."[74]

Section 7

Recommendations

Summary

Our main recommendations are as follows. Pfizer should cease lobbying for TRIPS-plus protection, acquiesce in the modifications to TRIPS proposed below, adopt greater flexibility in the degree to which it enforces its patent rights, adopt systematic and transparent tiered pricing policies, and increase its commitment to R&D into "Third World" diseases. Developed-country governments should agree to modify TRIPS to ensure developing countries greater flexibility in addressing their pressing health problems (notably by licensing generic manufacturers to produce low-price versions of patent-protected products). They should also fully support the UN Global Health Fund and establish a dedicated global research fund. Developing countries should resist pressures for TRIPS-plus legislation, make full use of the TRIPS safeguards, and increase commitments to health expenditure.

Pfizer's price cuts and philanthropy programs, though significant for their beneficiaries, do not represent an adequate response for the many other people in many countries who cannot afford the prices that Pfizer charges. Oxfam accepts that the global health crisis is complicated and cannot be resolved by reducing the price of medicines alone. However, price is a critical factor in defining who has access to medicines, and patents are a major upward influence on price.

Recent campaigns and media coverage of the issue of access to medicines has led to growing concern about the applicability of a global patent system to the needs of poor countries. Some progress has been made recently, including a range of targeted price cuts, the abandonment by the pharmaceutical industry of the South Africa case, and the U.S. government's removal of its complaint against Brazil from the WTO dispute mechanism. However, these advances should not distract attention from the need for reform of the TRIPS agreement and increased commitments to other global health initiatives.

The recommendations below outline what key players can and should do to address the problem of a global patent system that exacerbates an existing crisis and further reduces access to medicines.

Recommendations to Pfizer

In the interests not just of the poor people of the developing world, but also of the long-term health of the industry itself, Pfizer should adopt a more constructive leadership role, both through PhRMA and independently of PhRMA. We call on Pfizer to:

- recognize that the price of life-saving medicines in developing countries is linked to patents and TRIPS.

- refrain from using its lobbying power to exert pressure for TRIPS-plus regimes in all trade agreements including via USTR's Section 301 mechanism.

- acquiesce in modifications to TRIPS that achieve a greater balance between public health needs and the interests of companies and abide by the modified rules.

- abstain from enforcing patent rights in developing countries where to do so yields little or no commercial advantage in the country concerned and look favorably on requests for voluntary licenses where there are urgent public health needs. Patents confer the right to enforce exclusivity but do not impose the obligation to do so.

- where exclusivity is enforced, and as a *quid pro quo* for measures to prevent low-price drugs from leaking into rich country markets and the creation of the UN Global Health Fund, accept the establishment of a competitive global tiered pricing mechanism.

- participate creatively in research programs aimed at poor-country diseases by increasing its in-house proprietary research in response to a global R&D fund; and contributing to the proposed global research fund.

Recommendations to Governments and Multilateral Institutions

Oxfam believes that developed-country governments and multilateral organizations should:

- agree to modify TRIPS to allow developing countries more flexibility in the scope and duration of pharmaceuticals patents, easier compulsory licensing, and longer transition periods for compliance.

- accompany the above proposal with rigorous measures to address the legitimate concerns of the industry about leakage of generics or low-price patent-protected drugs to high-price industrialized markets and about prices in developing countries being used as a "benchmark" in other countries.

- establish a moratorium on all dispute actions that hinder the access of developing countries to life-saving medicines, particularly with regard to their use of compulsory licences and parallel imports.

- support the UN Global Health Fund with contributions as below:

Annex 1: Proposed composition of the Health fund based on approximate 2000 GNP figures

Source: OECD DAC website

Country	Proportion of fund based on approx GNP 2000 (US$m)		
US	4,0390	Belgium	970
Japan	20400	Sweden	930
Germany	7840	Austria	760
UK	6070	Norway	670
France	5400	Denmark	670
Italy	4430	Finland	510
Canada	2910	Greece	460
Spain	2320	Portugal	420
Netherlands	1600	Ireland	340
Australia	1560	New Zealand	170
Switzerland	1100	Luxembourg	80
		Total	**100000**

- establish an additional global research fund aimed in particular at new vaccines and treatments for HIV, malaria, TB, sleeping sickness, etc.

Recomendations to Developing Countries0

Oxfam calls on developing countries to:

- resist pressures and inducements from industrialized countries to adopt TRIPS-plus levels of intellectual property protection.

- increase commitments to essential social services, and, specifically, to increase health expenditure targets agreed upon at the African Summit on HIV/AIDS and related infections, held in April 2001.

- consolidate a concerted position on TRIPS reform to allow for more flexibility in the scope and duration of pharmaceutical patents, easier compulsory licensing procedures and parallel import uses, and longer transition periods for compliance to be directed at the G8 Meeting in Genoa in July 2001 and beyond.

- incorporate the full extent of TRIPS safeguards into their national legislation.

- make full use of compulsory licensing and parallel importing in their national medicines policies.

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[5] GlaxoSmithKline, financial presentation by J-P Garnier, February 19, 2001.

[6] Statistics for Pfizer in this section are mainly from its *Annual Report 2000*, accessible at www.pfizer.com.

[7] IMS Health reports audited worldwide pharmaceuticals sales at US$317b in 2000, and estimates total sales – including certain OTC products – at US$354 billion (www.ims-global.com).

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[12] Pfizer, *Midyear Report 2000*.

[13] Statistics are for 1998 and are taken from *World Development Report 2000/2001*, p. 277.

[14] UNAIDS, *Report on the Global HIV/AIDS Epidemic*, June 2000 and December 2000.

[15] WHO, *Report on Infectious Diseases 2000*, 'Overcoming Microbial Resistance.'

[16] Quotation is from WHO, April 25, 2000, press release 'Economic costs of malaria are many times higher than previously estimated.'

[17] R. Bonnel, HIV/AIDS: *Does it increase or decrease growth in Africa?* ACT Africa/World Bank, 2000.

[18] As reported in Erica Barks-Ruggles, "Brookings Policy Brief: Meeting the Challenge of HIV/AIDS." April 2001.

[19] WHO, *Report on Infectious Diseases 1999*, 'Removing Obstacles to Healthy Development.'

[20] WHO, *Report on Infectious Diseases 2000*.

[21] WHO, *World Health Report 2000*, Annex Table 8, 1997 data.

[22] WHO, *WHO Medicine Strategy 2000-2003*, Geneva, 2000.

[23] *World Development Report 2000/2001*, pp. 274-5.

[24] WHO, *Report on Infectious Diseases 2000*.

[25] WHO, *Financing Health in Developing Countries*.

[26] WHO Secretariat. Background paper for the WHO-WTO Secretariat Workshop, "More Equitable Pricing for Essential Drugs," April 2001.

[27] Executive Order 13155 issued by President Clinton in May 2000 prohibits the U.S. government from seeking the revision of any intellectual property law in sub-Saharan Africa that pertains to HIV/AIDS treatments as long as it is TRIPS-compliant. President Bush's administration has indicated that it has no plans to rescind this order.

[28] MSF, "Price Differences of Fluconazole: Consequences and Conclusions". Access to Essential Medicines campaign study, July 2000. Note: Pfizer takes issue with MSF's methodology. Comment from Pfizer to Oxfam, June 21, 2001.

[29] Scherer, Frederick M., *Industrial Market Structure and Economic Performance* (Chicago: Rand McNally), 1980.

[30] For example, see Schut, Frederick T. and Van Bergejik, Peter A.G., "International Price Discrimination: The Pharmaceutical Industry," *World Development* 14 (9): p. 1141-1150, 1986.

[31] MSF, "HIV/AIDS Medicines Pricing Report," July 2000.

[32] Instituto Brasileiro de Defesa do Consumidor e, Silver, L., Marques, A.R., and Araujo, A.C., "Comparacao Internacional de Precos de Medicamentos Essenciais da RENAME 2000." Report, University of Brasilia, December 2000.

[33] Between the early-1990s and late-1990s, the average US clinical development time for new drugs fell by 22% to an average of around 60 months (for 'priority' drugs – ie, those considered by the Food & Drug Administration to offer high therapeutic value – average development times fell further, to 54.1 months in 1998-9). In addition, regulatory approval times halved between 1993 and 1998, to just 10 months. Hence the average period for clinical development plus approval was less than 6 years at the end of the decade, compared with closer to 10 years at the beginning. (Source: Tufts University Center for the Study of Drug Development, September 2000 and October 2000 Impact Reports, available at www.tufts.edu/med/csdd)

[34] On Brazil's AIDS program, see www.aids.gov.br/politica/index.htm.

[35] *O Estado de Sao Paulo*, May 16, 2001.

[36] WHO, *Report on Infectious Diseases: Removing Obstacles to Healthy Development*.

[37] www.pfizer.com.

[38] Pascale Boulet, "Patent Protections of Medicines in Kenya and Uganda," MSF, April 2000.

[39] WHO, *World Health Report 2000*.

[40] "Adverse Reaction: AIDS Gaffes in Africa Come Back to Haunt Drug Industry at Home," *Wall Street Journal*, April 23, 2001.

[41] *The Economist*, April 21, 2001, p. 83.

[42] Meeting between Pfizer and Oxfam, New York City, June 4, 2001.

[43] "Facing the Challenge" can be found at www.gsk.com.

[44] For example: **Bristol-Myers Squibb** has promised to reduce the prices of ddI and d4T to about $500 per year in Senegal as part of AAI. **Boehringer-Ingelheim** will offer Viramune brand nevirapine free for a five-year period to developing countries for prevention of mother-to-child HIV transmission. **Glaxo Wellcome**, the first big company to announce a specific price reduction for HIV drugs in poor countries, has offered to reduce the cost of Combivir (AZT and 3TC) from about $16 per day in rich countries to $2 per day in selected poor countries. **Merck & Co**. has provided $3 million to the Harvard AIDS Institute for its Enhancing Care Initiative (ECI) in Brazil and Senegal. Merck has also given $1 million to upgrade the library of the University of Cape Town Medical School. Merck & Co. has announced a five-year, $50 million gift to the Republic of Botswana, in conjunction with the Bill and Melinda Gates Foundation, which is also giving $50 million. Merck has also signalled its intention to provide price cuts on indinavir and/or efavirenz (Crixivan and Stocrin) to Senegal. This is the first time Merck has explicitly abandoned its "one world, one price" stance. The Swiss giant **Roche**, makers of HIVID brand zalcitabine (ddC) and Invirase and Fortovase brands saquinavir, and marketers of Viracept brand nelfinavir to most of the world, has also promised price cuts under the UNAIDS program. **Abbott Laboratories** developed an agreement with Tanzania in late June 2000 and is providing "initial grants in Mbeya, an especially poor region in southwest Tanzania where AIDS is rampant." Source: Mark Harrington, "Brazil: What Went Right? The Global Challenge of Access to Treatment and the Issue of Compulsory Licensing." Paper presented at the Tenth National Meeting of People Living with HIV and AIDS, Rio de Janeiro, Brazil, November 3, 2000.

[45] Oxfam internal unpublished interview.

[46] Pfizer communication to Oxfam, June 21, 2001.

[47] Ibid.

[48] Ibid.

[49] www.opensecrets.org , Center for Responsive Politics.

[50] Ibid.

[51] www.pfizer.org.

[52] Belen Balanya, Anne Doherty, Olivier Hoedeman, Adam Ma'anit, and Eric Wesselius, *Europe Inc*. (Pluto Press, 2000).

[53] www.foei.org/LINK/LINK93/biotechlobby.html.

[54] Quoted in M. Santoro, "Pfizer: Protecting Intellectual Property in a Global Marketplace," Harvard Business School, 1992, p.7 (hereinafter referred to as 'Santoro').

[55] www.ustr.gov/outreach/advise.html.

[56] op cit. Santoro.

[57] P. Drahos and J. Braithwaite, *Information Feudalism*, (forthcoming 2002).

[58] P. Drahos, 'Global Property Rights in Information: The Story of TRIPS at the GATT,' *Prometheus*, vol. 13, p. 7-8, 1995.

[59] The membership of the IPC was: Pfizer, IBM, Merck, General Electric, Du Pont, Warner Communications, Hewlett-Packard, Bristol-Myers, FMC Corporation, General Motors, Johnson & Johnson, Monsanto, and Rockwell International.

[60] Intellectual Property Committee, "Basic Framework of GATT Provisions on Intellectual Property," Keidanren and UNICE, June 1988.

[61] Edmund T. Pratt Jr., "Pfizer Forum: Intellectual Property Rights and International Trade," *The Economist*, May 27, 1995, p. 26.

[62] FDCH Congressional Testimony, March 13, 1996.

[63] Ibid.

[64] Santoro, p. 9.

[65] The three categories are Priority Foreign Countries, Priority Watch List countries, and Watch List countries.

[66] Ministerio da Justica, Secretaria de Defensa Economica. The drugs are: Citalor (atorvastatin), a cholesterol-lowering drug; Diabinese (chlorporpamide), a drug used for the treatment of diabetes; Feldene (piroxicam), an anti-inflammatory drug; Norvasc (amlodipine), a cardiovascular drug; Terramicina (oxitetraciclina), an antibiotic; Tralen (thioconcazol), an antifungal for gynecological use; Viagra (sildenafil), a treatment for impotence; Vibramicina (doxycicline), an antibiotic used widely in treating sexually transmitted diseases; and Zoltec (fluconazol), an anti-fungal agent used widely both in gynecology and in treating infections associated with AIDS.

[67] IMS Health. *Mercado Farmacêutico Brasileiro*. Sao Paulo, January 2000 and December 1998.

[68] Interviews by Professor Lynn Silver, University of Brasilia, of Aldo Rebelo, Federal Deputy, Brazilian Congress; Sissi Santos Pereira, Staff Advisor, Brazilian Senate; and Cicero Gontijo, Professor of law, Getulio Vargas Foundation May 2001.

[69] J. Lanjouw and I. Cockburn, "New Pills for Poor People? Empirical Evidence After GATT," *World Development*, vol. 29, 2001, p. 268.

[70] Speech to the U.S. Council for International Business, Conference on Intellectual Property, March 1995.

[71] This is not to imply that Oxfam endorses current pricing policy in the U.S.

[72] "Implausible Denial – Why the Drug Giants' Arguments on Patents Don't Stack Up," April 2001 (available at www.oxfam.org.uk/cutthecost).

[73] *The Lancet*, vol. 357, p 243, January 27, 2001.

[74] David E. Sanger, "A Grand Trade Bargain," *Foreign Affairs*, January/February 2001.

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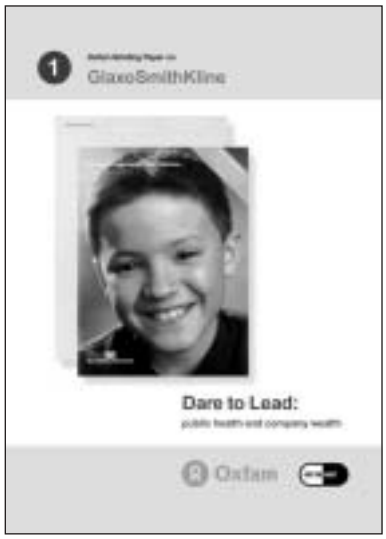
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