

Robbing the Poor to Pay the Rich?

How the United States
keeps medicines from
the world's poorest

Impressive advances in medicine and technology have boosted health and extended life expectancy – but not for everyone. Vital new medicines for diseases such as HIV/AIDS are priced out of reach of the millions of sick people in the developing world, in part due to global patent rules which restrict the availability of affordable generic versions of patented medicines. In 2001, all members of the World Trade Organization adopted the ‘Doha Declaration’, promising to prioritize public health over private patent rights and to promote ‘access to medicines for all’. This paper examines how the government of the United States is contravening this commitment by using technical assistance, bilateral and regional trade agreements, and the threat of trade sanctions to ratchet up patent protection in developing countries. This policy benefits the influential U.S. pharmaceutical industry while pushing medicines further out of the reach of poor people.

Executive summary

In 2001, WTO members unanimously adopted the 'Doha Declaration',¹ which affirmed the primacy of public health over international patent rules. Trade ministers recognized that WTO patent rules – known as TRIPS – lead to higher drug prices, placing medicines out of reach of patients in poor countries and undermining public health. They made a commitment to interpret patent rules in a way that prioritized health standards, and to ensure that countries too poor to buy branded drugs and unable to make cheap generic substitutes could obtain medicines more easily.

The United States signed the Doha Declaration, promising to promote 'access to medicines for all'.² But in the two years since Doha, it has not only failed to uphold this commitment but has actively undermined the letter and spirit of the Declaration. The U.S. Trade Representative is pursuing standards of patent protection which go far beyond WTO patent rules, and it is doing so regardless of the devastating impact that this could have on the capacity of developing countries to treat health problems such as Acquired Immune Deficiency Syndrome (AIDS).

Oxfam believes the U.S. government is pursuing this pro-patent agenda on behalf of its powerful pharmaceutical lobby, PhRMA.³ The industry has an interest in strong patent protections, which limit generic competition and therefore protect its market share and profits. In 2000, the industry contributed approximately \$20,142,583 in campaign contributions, 76 per cent of which went to the Republican Party.⁴ In 2003, the industry gave \$29,371,406, with \$21,719,527 of that money going to Republicans.⁵ In addition, it spends approximately \$120 million each year on lobbying. This is a drop in the ocean compared with its yearly sales: an estimated \$400 billion in 2002. The ten largest U.S. drug companies made \$35.9 billion in profit in 2002, with a rate of return for shareholders of 27.6 per cent, more than two and a half times the Fortune 500 average of 10.2 per cent.⁶

¹ 'We agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health ... we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all.' Doha Declaration on the TRIPS Agreement and Public Health, paragraph 4.

² Ibid.

³ The lobby group for the U.S. pharmaceutical industry is called PhRMA (Pharmaceutical Research and Manufacturers of America).

⁴ 'The Other Drug War: Big Pharma's 625 Washington Lobbyists', Public Citizen, 2001.

⁵ www.opensecrets.org website.

⁶ Public Citizen, June 2003. 'Drug Industry Profits 2002: Hefty Pharmaceutical Industry Margins Dwarf Other Industries.'

Fourteen million people die each year from infectious diseases, and more than 42 million people are living with HIV/AIDS, including 3.2 million children under the age of 15, the majority in developing countries.⁷ And patients in developing countries now account for 59 per cent of the 56.5 million annual global deaths from non-communicable diseases such as cardiovascular disease, cancers, diabetes, respiratory disease, obesity, and others.⁸

Much of this suffering and death could be prevented if people had regular access to medicines, yet one-third of the world's population does not. Many factors are responsible, including poverty, lack of finance, and poor health-service infrastructure – but the high cost of new patented medicines is also a key factor. The absence of cheap generic versions of these medicines means that poor people must simply go without the drugs that could save or prolong their lives. The most notorious example is medicines to treat HIV/AIDS, but the problem will extend to all new medicines whether for drug-resistant strains of existing killers such as TB, malaria, and pneumonia, new improved treatments for hepatitis, cancers, diabetes, or treatments for new emerging diseases, such as Severe Acute Respiratory Syndrome (SARS) or anthrax.

Poor countries with fewer resources to dedicate to healthcare and medicines need access to the cheapest drugs available to fight such problems of public health. But the cheapest generic versions of new patented drugs are being blocked from developing-country markets by U.S. trade policies on intellectual property, at the urging of the drug companies that benefit from the monopoly position that patents confer.⁹

During the two years since Doha, the U.S. has contravened the goal of the Declaration – 'access to medicines for all' – by pressuring developing countries to implement 'TRIPS-plus measures': patent laws which go beyond TRIPS obligations and do not take advantage of its public-health safeguards. The USA does this in a number of ways. It provides biased technical assistance in countries such as Uganda and Nigeria, which benefits its own industry by increasing drug prices and limiting the availability of generics, but reducing access. It uses bilateral and regional free trade agreements to ratchet up patent protection in developing countries. It has recently concluded free trade agreements with Chile and Singapore and is using the high intellectual property standards in the latter as a model for negotiations on the FTAA (Free Trade Area of the Americas (see OI briefing paper 'From Cancun to Miami: the FTAA threat to development in the hemisphere', November 2003) and with Central American, Southern African, and other countries. And lastly,

⁷ Center for Disease Control (CDC) website.

⁸ WHO website (<http://www.who.int/mediacentre/notes/2003/np21/en/>).

⁹ Developing countries have access to cheap off-patent generic medicines to treat many diseases, and some of them have access to generic versions of medicines that are under patent in certain countries but produced and consumed in other countries that do not yet offer patent protection for pharmaceutical products. But new improved medicines coming to market are likely to be patented and therefore excessively priced. This will be the case for new drugs to treat AIDS, drug-resistant TB or other infectious diseases, increasing problems like cancer and diabetes, and new health problems such as SARS.

the U.S. bullies countries into increasing patent protection by threatening them with trade sanctions under section 301 of the Trade Act of 1974; nearly all those targeted are developing countries, including countries in compliance with their WTO obligations. The Costa Rican Pharmaceutical Industry estimates that the implementation of such TRIPS-plus patent rules would mean an increase in the cost of medicines of up to 800 per cent, because these rules would seriously restrict competition from generics.

At the WTO, the U.S. pressured developing countries to accept an unnecessarily restricted and complex deal which was intended to safeguard access to generic drugs for countries that are too poor to buy patented drugs and which lack domestic drug-production capacity. Action on this issue was promised as part of the Doha Declaration, but regrettably the U.S. and other rich countries rejected a simple solution initially proposed by developing countries, the World Health Organization (WHO) and NGOs. The U.S. has also pressured Cambodia (the first of the least-developed countries [LDCs] to join the WTO since its foundation) to agree to introduce patenting now, even though the Doha Declaration permitted the LDCs to defer the introduction of pharmaceutical patenting until at least 2016.¹⁰

The pro-health interpretation of international patent rules was a key promise made by rich countries in launching the current 'Doha Round' of trade talks. This Round has been dubbed the 'Doha Development Round', since it was meant to address the needs and interests of poorer countries. But developing countries are now rightly skeptical, doubting that their rich-country trading partners – especially the U.S. – ever intended to focus on development. In the two years since Doha, the U.S. has been excessively responsive to industry interests, while failing to consider the importance of generic medicines for fighting public-health problems in developing countries that lack healthcare resources. Unless the U.S. adjusts its trade policies to reflect its commitment at Doha, medicines will be priced further out of reach of poor patients. Millions of people will suffer or die needlessly because the U.S. government refuses to look beyond the short-term commercial interests of its drug lobby.

Oxfam recommends the following measures:

- WTO members should ensure the simplification of the final TRIPS amendment aimed at lifting restrictions on the export of affordable generic versions of new drugs to countries without drug-production capacity. Unnecessary red tape should be removed, and there should be no mandatory limits on country eligibility, or on the diseases for which such medicines can be procured, in keeping with the Doha Declaration. WTO member states should amend their legislation accordingly.

¹⁰ Negotiations over Cambodia's accession have just finished. Cambodia is required to introduce drug patenting in 2007. In practice, generic competition for new medicines will be eliminated immediately, because Cambodia has agreed to introduce restrictions on the use of the clinical trial data needed for the registration of new medicines. This will delay the entry of generics into the market for five years.

- The U.S. should stop using the threat of trade sanctions to bully countries into adopting 'TRIPS plus' intellectual property protections. TRIPS-plus rules further limit the availability of affordable generics in countries where they are urgently needed, and they contravene the Doha Declaration.
- The U.S. should also stop using its bilateral trade agreements such as CAFTA, regional agreements such as the FTAA, or negotiations over to WTO accession to pressure developing and least-developed countries to adopt TRIPS-plus patent rules.
- The U.S. should provide technical assistance to developing countries that will benefit public health and access to affordable medicines, rather than the interests of the pharmaceutical industry.
- Developing countries should resist pressures to implement TRIPS-plus measures, and should make full use of the TRIPS flexibilities, including but not limited to the recent WTO deal, in order to gain access to medicines, in line with the Doha Declaration
- The international community must continue to monitor the health impacts of the TRIPS Agreement, and should consider further future reforms to the Agreement in order to give developing countries greater freedom to decide the appropriate length and scope of patents protection for medicines based on the needs of public health. More broadly, evidence from authoritative sources indicates the need for a substantive review of the entire TRIPS Agreement in the light of its detrimental impact on innovation, access to knowledge-based goods, and development.

Robbing the poor to pay the rich

Two years ago, the United States and all other WTO members agreed that public health should take priority over patent rights, endorsing the 2001 'Doha Declaration on TRIPS and Public Health', which endorsed 'access to medicines for all' (see Box 1). Lauded as a victory for developing countries, this important political commitment has been consistently undermined by American trade policies and practices which restrict access to affordable drugs and contradict this pro-health rhetoric. Oxfam believes that such policies are the result of lobbying by the U.S. pharmaceutical industry, which induces the administration to protect industry interests rather than fulfill its promises to developing countries.

Fourteen million people die each year from infectious diseases, and 42 million people now live with HIV/AIDS, including 3.2 million children under 15.¹¹ The great majority of these patients live in poor countries where the medicines that would save or prolong their lives are priced out of reach, in part due to patent provisions which restrict the availability of cheap generic versions of patented drugs. And patients in developing countries are increasingly suffering from non-communicable diseases and health problems previously associated with rich countries. According to the World Health Organization, 'cardiovascular disease, cancers, diabetes, respiratory disease, obesity and other non-communicable conditions now account for 59 per cent of the 56.5 million global deaths annually and 45.9 per cent of the global burden of disease. The majority of chronic disease problems now occur in developing countries'.¹²

The U.S. government has indicated its willingness to back the efforts of sub-Saharan Africa countries to fight AIDS, malaria, and tuberculosis, by not enforcing its companies' patent rights under certain conditions.¹³ But poor countries with few resources to

¹¹ Center for Disease Control (CDC) website.

¹² WHO website (<http://www.who.int/mediacentre/notes/2003/np21/en/>).

¹³ 'The U.S. pledged to permit these [sub-Saharan Africa] countries to override patents on drugs produced outside their countries in order to fight HIV/AIDS, malaria, tuberculosis, and other types of infectious epidemics, including those that may arise in the future.' USTR press release 'U.S. Announces Interim Plan to Help Poor Countries fight HIV/AIDS and other Health Crises in Absence of WTO Consensus,' December 20, 2002.

dedicate to healthcare healthcare and medicines need access to the cheapest drugs available to fight a variety of public-health problems, including the most damaging infectious diseases.

The introduction of generic competition is crucial to bringing down drug prices in a sustainable way. Patent protections delay the introduction of cheap generics to drug markets, granting big pharmaceutical companies a monopoly over their product and thus enabling them to set high prices for it. Access to generics, which tend to be much cheaper than branded drugs, is especially important in countries where resources devoted to healthcare healthcare are scarce, and in places where people have to pay out of their own pockets for medicines, due to an absent or non-functioning public healthcare system.

Oxfam research has shown that one clinic in Uganda, the Joint Clinical Research Center, was able to triple the number of AIDS patients receiving antiretroviral (ARV) therapy by importing generic medicines and using generics in the place of more expensive branded drugs.¹⁴ The low-cost generics stretched available funds much further so that more lives could be saved.

In Brazil, the government has provided people living with HIV/AIDS with access to treatment by using local generic production and competition to bring down prices. As a result, 90,000 AIDS deaths and 358,000 AIDS-related hospitalizations were avoided between 1996 and 2002, and the government saved \$2 billion.

The importance of generics was emphasized earlier in 2003 by two senior World Bank officials in an editorial: *'One day's supply of patented antiretrovirals for an AIDS patient typically costs \$30. This is of course out of the question for the nearly three billion people who live on less than \$2 a day. Generics are usually much cheaper than patented drugs, and the threat of competition has reduced prices of both in some places. Hetero, a manufacturer of generics in India, offers HIV drugs for just 55 cents a day.'*¹⁵

¹⁴ Oxfam Briefing Paper No 26, Generic Competition, Price and Access to Medicines: the case of antiretrovirals in Uganda, 2002.

¹⁵ Ibid.

BOX 1**The impact of TRIPS on the ten million Egyptians with Hepatitis C**

'My condition started deteriorating gradually, with progressive fatigue, bone aches, and patches of blood over my belly and legs. I am not able to do housework and care for my family.' (Sanna Taha Eisa, housewife with three children)

'Maybe if I took the full course, it could have benefited me more. Anyway I am luckier than my younger brother, whose condition deteriorated rapidly until he died one year ago.' (Abdel Latif, government employee)

The Hepatitis C virus causes debilitating chronic damage to the liver, cirrhosis and cancer. At 18 per cent, Egypt has the highest rate of infection in the world, placing a huge burden on the national health budget. As in the case of HIV/AIDS, new drugs and combination therapies are becoming more effective, but they are extremely expensive. The basic medicine for treating Hepatitis C is interferon; however, only 16 per cent of patients maintained a sustained viral response. Soon afterwards, the introduction of ribavirin in combination therapy led to an increase in the success rate to around 41 per cent.

Recent studies show that a new form of interferon called 'peginterferon', in combination therapy with ribavirin, increases the success rate to between 54 and 70 per cent. The new drug requires to be injected only once a week, rather than the frequent injections that are necessary for the administration of interferon. This means better adherence to treatment regimes, and a continuous, improved viral response. Although these medicines are available in Egypt, the price is prohibitive for most patients. It costs US\$ 6000 to treat one patient with a 24-week course of this latest drug.

Because Hepatitis C is present in the industrialized world, there is a market stimulus for research to develop medicines with greater efficacy and fewer side effects, and there are at least a dozen new medicines already in the pipeline. With TRIPS patent provisions in force, these new drugs will be patented and will undoubtedly be priced out of reach of patients in developing countries such as Egypt. Because Egypt has some manufacturing capacity, but not sufficient to produce the latest drugs, it may prove difficult for it to qualify under the new WTO deal to import cheap generic versions of these new medicines from other countries. Instead it will have to pay the high price of the patented new medicines – or its people must do without.

While patent protection typically leads to higher drug prices and lower availability of generics, it is not the only cause of inadequate healthcare in the developing world. A range of factors – including lack of funding, inadequate healthcare infrastructure, and paltry research and development (R&D) concerning neglected diseases – are responsible for poor healthcare in the developing world. But the high cost of new patented medicines is one of them and it must be addressed. The United States made a commitment to do so when it adopted the Doha Declaration, and Congress

affirmed this commitment by instructing the U.S. Trade Representative (USTR) to respect the Declaration in U.S. trade policies and practices.¹⁶ This paper discusses the USA's disappointing performance in upholding this commitment since the commitment was made two years ago, examining how the administration protects the aims of the drug companies instead of promoting access to affordable medicines.

International patent rules and public health

In the early 1990s, the United States – backed by its industry lobbies, which depend on strict protection of intellectual property for their continued profitability – successfully obtained the inclusion of patent rules in the WTO trading system. These rules – known as the 'TRIPS Agreement'¹⁷ – are recognized by experts on intellectual property (IP) as being highly favorable to IP rights holders, often at the expense of public policy and development goals such as improving access to medicines for the poor.

The TRIPS Agreement, the most dramatic extension of intellectual property rights in more than a century, requires WTO members to introduce a specified minimum level of intellectual property protection for copyright, patents, and trademarks, including enforcement mechanisms. It obliges countries to offer a patent term of at least 20 years on all products and processes, including pharmaceuticals. Developing countries which did not have drug patents in the past have been given until 2005 to comply with the Agreement. The Doha Declaration extended the deadline for compliance by least-developed countries (LDCs) to 2016, after which they may apply individually for deferment. It has been estimated that the economic cost of TRIPS for developing countries will exceed \$40 billion a year,¹⁸ while the legal and administrative costs of providing the protections that the Agreement requires will amount to \$1.5-2 million per country.¹⁹

¹⁶ The Kennedy amendment to the Fast Track negotiating mandate instructed the USTR to, among other objectives, 'respect the Declaration on TRIPS and Public Health' when negotiating intellectual property provisions in free trade agreements.

¹⁷ TRIPS is the WTO Agreement on 'Trade Related Aspects of Intellectual Property Rights'. It forms part of the 'single undertaking' that concluded the Uruguay Round in 1994.

¹⁸ Calculated by Oxfam using World Bank figures.

¹⁹ World Bank, 2002.

Cheap generic equivalents of patented medicines are currently produced and in some cases exported by countries that do not yet have to offer patent protection to pharmaceutical products under TRIPS. This is the case with the low-cost antiretrovirals made by India, which have so drastically reduced the prices in Africa. Until the Indian generics came on to the market at \$300 per patient per year, the big drug companies were selling the patented equivalents for around \$10,000 per patient per year. As a result of global public concern and the development of generic substitutes, the brand-name companies subsequently dropped their prices to around \$900, and more recently, at least one company has substantially lowered its prices again. Under TRIPS, new pharmaceutical products will be under patent in more and more countries, preventing the production, export, import, and sale of generics in these markets for at least twenty years. Because generics typically cost a fraction of the price of patented drugs, the imposition of laws that limit their availability – above all in poor countries – poses a danger to public health.

Pharmaceutical companies tend to charge high prices for their branded or patented products even in markets where the majority of people are very poor. This is because they make their greatest profits by selling to local elites. These profits are earned at the expense of supplying the majority of patients with the medicines.

Box 2 Flexibilities in the TRIPS Agreement

Article 7 sets out the ‘**principles**’ of TRIPS, stating that *‘the protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation ... in a manner conducive to social and economic welfare, and to a balance of rights and obligations’*.

Articles 6, 8, 30, and 31 set forth the limited exceptions to TRIPS patent rules. These exceptions are called ‘**public health safeguards**’ and may be used to promote public health. For example, countries may use parallel importation or the compulsory licensing safeguards to obtain cheaper patented drugs or generic copies of patented medicines or when facing public-health problems.

TRIPS provides flexibility for members to use parallel importation to obtain affordable medicines. Under **Article 6**, countries can decide whether or not to provide for international exhaustion of patents (which allows importation of a patented product placed on a foreign market at a lower price).

Article 30 of TRIPS allows members to ‘provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner’.

Article 31 governs use of compulsory licensing, a process that may be used by governments to temporarily override a patent and authorize production of copies of patented medicines in the public interest (for example, if the country is faced with a public health problem). Developing countries have complained of section (f) of Article 31, which limits the export of drugs made under compulsory license; after 2005, countries that manufacture and export generics will be unable to do so under the original TRIPS provision, cutting off a key supply of affordable medicines for the poorest countries.

Intellectual property (IP) laws are supposed to balance the incentive for innovation with the public interest in the development and availability of new products and technologies. To help to maintain this balance, patent laws contain 'safeguard' provisions which limit the rights granted to patent holders when these conflict with the public interest. For example, patent laws contain provisions allowing governments to authorize the introduction of generic competition, for example when a patent holder has abused its monopoly position and engaged in anti-competitive conduct, or for reasons of public health – for example, if the price of medicines is too high or the supply is limited. This safeguard is called 'compulsory licensing'. The TRIPS Agreement clearly states that it is up to governments to determine the grounds for compulsory license. This safeguard is important, because even if a country does not wish to use compulsory licensing, the fact that it is permitted to do so is a vital bargaining chip when negotiating drug prices with the big international companies, as Brazil has shown by obtaining patented antiretrovirals for treating AIDS at greatly reduced cost. However, as we will see below, the U.S. government has tried to prevent developing countries from using these safeguards.

USTR's 'TRIPS-plus' agenda

Two years after it endorsed the Doha Declaration, the U.S. administration continues in a number of ways to contravene this commitment; in Oxfam's opinion, it does so at the behest of Pharmaceutical Research and Manufacturers of America (PhRMA). At the WTO it has taken positions identical to PhRMA on a deal aimed at improving access to generic medicines for countries that lack drug-production capacity (the 'paragraph 6' problem raised in the Doha Declaration). It rejected a simple solution initially proposed by developing countries and supported by the WHO, trying instead to restrict the deal to certain diseases and only the poorest countries.

Fortunately, emboldened by the Doha Declaration, developing countries refused to accept restrictions on disease coverage, which would have very damaging consequences for public health in the future. However, due to pressure from the USA and other rich countries, the final solution is unnecessarily complex and will prove difficult for developing countries and generic industries to use. Nor will it solve the deeper problems that TRIPS creates for the production of generic substitutes. Unless the rules are relaxed in developing countries, or unless countries are allowed to use compulsory licensing in a more routine manner, the supply of affordable generic versions of new medicines is likely to dry up in the longer term.

The USTR has also redoubled its efforts to have TRIPS-plus provisions instituted in developing and least developed countries. TRIPS-plus provisions extend protection to patent holders beyond that offered under WTO rules, by eliminating or weakening the safeguards permitted in TRIPS, and by restricting generic competition through various regulatory requirements. The U.S. does this by (1) providing biased TRIPS-plus technical assistance which favors industry interests, (2) negotiating TRIPS-plus provisions in regional and bilateral free trade agreements such as the US-Singapore agreement, and (3) threatening countries with trade sanctions when industry complains that they provide what it considers inadequate protection of intellectual property.

The USTR's intention is to seek harmonization of all countries' IP laws with U.S. standards of intellectual property protection.²⁰ The U.S. has the highest level of IP protection in the world, and its laws far exceed the patent rules under TRIPS; in effect, 'harmonization'

²⁰ The drug industry communicates its positions and priorities to the U.S. government through participation in USTR advisory committees, via submission of reports related to Special 301 (a section of the 1974 U.S. Trade Act that provides for sanctioning of countries deemed to provide inadequate protection to American intellectual property), via regular lobbying, and through participation in government bodies such as the President's Commission on HIV/AIDS. The membership of the 'IFAC 3' advisory committee to USTR, which advises the agency on intellectual property provisions in trade agreements, includes a Pfizer Vice President, a Vice President of PhRMA, and the Director of Public Policy for Merck & Company. This is the most important U.S. advisory committee on IP issues yet it consists only of industry representatives whose companies rely on strict IP protections. Commenting on the US-Singapore FTA, the group wrote: 'the resultant level of intellectual property protection that it contains should not be viewed as setting any ceilings ... rather, our goal in the negotiation of an FTA is to set a new baseline for future FTAs', advocating what is clearly a TRIPS-plus agenda (IFAC 3 report, 2003).

here means 'TRIPS-plus'. The U.S. is a wealthy industrialized country, with IP laws designed in keeping with its economy and regulatory systems; these laws make no sense when implemented in developing and least-developed countries. To make matters worse, USTR is tabling US-style intellectual property provisions in trade negotiations, but omitting the safeguards that exist in American law to balance the rights of patent holders with the public interest.²¹ Congressman Waxman recently commented on U.S. patent provisions:

²¹ Representative Henry A. Waxman, 'Hatch-Waxman and International Trade' (Testimony on the Chile and Singapore Free Trade Agreements), June 10, 2003.

This system works in this country because most people in the U.S. have health insurance that pays for essential drugs and because we have a healthcare safety net to assure that the poorest in our society are not left without medical care and treatment. But to impose such a system on a country without a safety net, depriving millions of people of life-saving drugs, is irresponsible and even unethical. In developing countries, we must do everything in our power to make affordable drugs for life-threatening diseases available now.²²

Countries at earlier stages of development tend to be imitators, not innovators. Many rich countries only implemented patent protection relatively recently, and before that they freely copied technologies from other countries. Strict IP protection is often not appropriate to the circumstances of developing countries and may be harmful to their development, since patent rules limit their access to new technologies by giving the innovator a twenty-year monopoly over use of the new product or technology. This negative relationship between strong IP protection and development was the focus of a 2002 expert study commissioned by the UK government. The commission wrote: *'standards of IP protection that may be suitable for developed countries may produce more costs than benefits when applied in developing countries, which rely in large part on knowledge generated elsewhere to satisfy their basic needs and foster development'*.²³

The TRIPS Agreement imposes obligations on developing countries that are often not in their best interest. TRIPS-plus provisions, which favor patent holders over the public interest to an even greater extent than WTO rules, can spell disaster for public health in poor countries.

TRIPS-plus technical assistance

The U.S. administration undermines the Doha Declaration by providing technical assistance that encourages countries to ratchet up their patent laws and limit competition from generic equivalents. In this way, the administration acts behind the scenes to encourage the adoption of TRIPS-plus laws in developing and least-developed countries. Such assistance is marketed as neutral advice on drafting

²² Ibid.

²³ UKCIPR website (www.iprcommission.org). Executive summary of UKCIPR report, 2002.

IP laws and is provided through USAID, other U.S. agencies, and the World Property Organization (WIPO), a UN body with a strong bias in favor of protecting intellectual property.

U.S. technical assistance was behind Uganda's TRIPS-plus Industrial Property Bill of 2002, which was introduced following consultation with USAID and an affiliated consulting firm. Uganda, a least-developed country, has until at least 2016 to comply with the TRIPS Agreement. This bill would make its laws TRIPS-compliant earlier than that, restricting access to generics before the country is legally obliged to do so. Pressure from healthcare activists and unease in parts of government have prevented adoption of the law and made it the source of much controversy in a country struggling to deal with AIDS. American TRIPS-plus technical assistance recently surfaced in Nigeria also, where USAID was advising the country to implement legislation that would have blocked the Nigerian government from using the health safeguards in TRIPS. Last-minute media and advocacy work by healthcare activists and NGOs exposed what was going on, and the project was halted.

Needless to say, the U.S. pharmaceutical lobby wholeheartedly supports the provision of TRIPS-plus technical assistance, noting that '*capacity building is a critical factor in achieving the PhRMA IP priority areas*'.²⁴ And PhRMA has even indicated its willingness to help the U.S. in providing assistance with revision of domestic IP laws so they exceed the requirements of the TRIPS Agreement: '*PhRMA members hope their efforts can complement stepped-up ... capacity building in developing countries. For example, PhRMA is working closely with the Government of Jordan to implement a best practices model for effective data exclusivity and linkage between the industrial property and health regulatory authorities.*'²⁵

Clearly, industry believes that 'capacity building' means enhancing intellectual property laws and the country's enforcement of them, not building the capacity of the country to identify its public-health interests and then set appropriate levels of IP protection. The US-Jordan Free Trade Agreement is widely recognized by experts to contain patent provisions that are TRIPS-plus, so PhRMA is in essence offering to help this and other developing countries to institute high levels of patent protection which match the industry's

²⁴ PhRMA Special 301 Submission, 2003.

²⁵ Ibid.

key goals in international patent rules. A developing country, Jordan does not have to comply with even minimum TRIPS requirements until 2005 – yet thanks to this bilateral FTA and technical assistance, its patent system will soon reflect TRIPS-plus standards.

Bilateral and regional free trade agreements (FTAs)

Bilateral and regional negotiations constitute easy opportunities for the U.S. to ratchet up patent protections, since USTR can provide access to the U.S. market, worth \$11 trillion, in exchange for signing up to TRIPS-plus provisions, thus fully exploiting U.S. economic and diplomatic influence over smaller nations. When developing countries sign up to TRIPS-plus measures, they are signing away the gains made under the Doha Declaration and paragraph 6 deal.

Box 3 Industry aims in trade rules: 'TRIPS-plus' to eliminate generic competition

TRIPS-plus agenda

'We strongly support inclusion of ... measures that build on and enhance the standards of the TRIPS Agreement and recent bilateral agreements between the United States and other countries' – '[it is] necessary to bring the intellectual property system of Morocco up to levels that approximate the standards of protection available in the United States.' (PhRMA Comments on US-Morocco FTA, June 17, 2003)

(1) Limit compulsory licensing

'Use of compulsory licensing, while included within the flexibilities of the WTO TRIPS Agreement, should only be used in cases of true market failure ... we seek limitation to the use of compulsory licensing.' (PhRMA Special 301 Submission re: SACU, 2003)

(2) Protect test data

'Effective protection for commercially sensitive and confidential clinical dossiers associated with applications for marketing approval (data exclusivity) ... remains a critical priority for PhRMA members.' (PhRMA Special 301 Submission, 2003)

(3) No generics approval until patent expiry

'We urge the United States to ask South Africa to provide explicit provisions that will oblige the relevant Government authorities to ensure [linkage] ... removing the possibility that generic copies will be able to enter the market during the term of the patent.' (PhRMA Special 301 Submission re: SACU, 2003)

(4) No parallel importation

PhRMA seeks 'standards that ensure that patent rights will not be exhausted by acts that occur outside the territory of each country.' (PhRMA Comments on US-Morocco FTA, June 17, 2003.

The U.S. recently concluded free trade agreements with Chile and Singapore, and is pursuing FTAs with countries in Central America (CAFTA), countries in the Southern African Customs Union (SACU), countries in the Western Hemisphere (FTAA), Morocco, Thailand, the Dominican Republic, and ASEAN (through the Enterprise for ASEAN Initiative). The Singapore and Chile agreements were approved in late July 2003, despite some lawmakers' concerns regarding the TRIPS-plus nature of some of the provisions, particularly those in the US-Singapore FTA, which contains very high levels of patent protection. USTR has announced its intention to use the IP chapter in Singapore as a template for future FTAs. The administration is clearly pursuing a TRIPS-plus agenda outside of the WTO: *'The United States is committed to a policy of pursuing increased protection of intellectual property rights ... through the negotiation of free trade agreements. We are pleased that the recently concluded free trade agreements with Chile and Singapore ... provide for higher levels of intellectual property protection in a number of areas covered by the TRIPS Agreement.'*²⁶

The US-Singapore Free Trade Agreement

The pharmaceutical industry has lauded the US-Singapore Free Trade Agreement, stating in the report of the Industry Functional Advisory Committee 3 (IFAC3) that *'it establishes key precedential provisions to be included in other FTAs now being negotiated, including the FTAA'*.²⁷ Below are listed TRIPS-plus provisions included in the US-Singapore FTA, along with an explanation of how they exceed the patent protections in TRIPS. These TRIPS-plus measures all strongly reflect the stated aims of PhRMA in free trade negotiations, and are meant to restrict generic competition.

(1) Limits on compulsory licensing. This FTA restricts this important right, a key element in balancing the interests of rights

²⁶ USTR Special 301 Report, 2003.

²⁷ IFAC report on US-Singapore FTA, p 1. The 'Industry Functional Advisory Committee 3' advises the USTR on intellectual property chapters of free trade agreements and is composed of representatives of various knowledge industries dependent on strong IP protections.

holders and the wider community in IP systems. Since compulsory licensing is a crucial way of introducing generic competition and thus reducing drug prices, limitations on its use would restrict access to affordable drugs. Also, the threat of compulsory licensing has been used by countries such as Brazil to bargain with drug companies for lower prices on patented medicines.

TRIPS gives governments complete freedom to determine the grounds for using compulsory licenses, including the need to address public-health problems. The US-Singapore FTA, however, limits use of compulsory licensing to remedy anti-trust violations, to national emergencies, and for public non-commercial use. This prevents use of compulsory licenses to gain access to affordable medicines for a range of important diseases, and prevents generic companies from supplying the private sector under compulsory license – even though this is where many uninsured people (such as poor people and senior citizens) buy their medicines out-of-pocket.²⁸ And it sets a higher standard of compensation to rights holders than that contained in the TRIPS Agreement, requiring that the rights holder be paid ‘reasonable and entire’ rather than ‘reasonable and adequate’ compensation when compulsory licensing is used.

(2) Five years of ‘data exclusivity’ for pharmaceutical products.

This provision in the FTA means that for the first five years following regulatory approval for the product, there is an obligation of ‘non-reliance’ on the data submitted by the patent holder. This prevents the regulatory authority from using the clinical trial data to assess an equivalent generic product for marketing approval, thus considerably delaying the entry of the generic into the market and putting up its cost. The TRIPS Agreement says only that signatories must protect patent holders’ data from ‘unfair commercial use’; it does not specify that regulatory authorities are unable to use the data when assessing a bioequivalent generic product for any period of time following registration.²⁹

²⁸ In developing countries, most people buy medicines in the private sector, in the absence of adequate public healthcare systems. Extending this precedent to agreements with poor countries would seriously limit people’s access to affordable drugs produced under compulsory license.

²⁹ The U.S. has persuaded Cambodia, expected to be the first LDC to join the WTO following its foundation, to introduce a similar ‘data exclusivity’ provision immediately, followed by a fully TRIPS-compliant patent system by 2007, nine years before TRIPS requires. All other developing countries seeking WTO accession, including many LDCs such as Nepal, Ethiopia, and Yemen, are being pressured by the U.S. to make similar TRIPS-plus commitments.

(3) Linkage of regulatory approval for generics with patent status. Under this provision, generics manufacturers may have to wait until patent expiry to obtain marketing approval, meaning that they cannot be approved and ready to enter the market immediately upon patent expiry. Typically, generic producers obtain marketing approval early, so that following expiry they can immediately introduce their product. Immediate availability of the cheaper generic medicine benefits consumers, since drug prices typically decrease dramatically once there is competition. The Singapore FTA also extends the patent period beyond 20 years to compensate for delays in regulatory approval. A twenty-year period of monopoly is more than enough for patent holders to benefit from their innovation, especially since the R&D phase (when the product is patented but not yet ready for marketing) is getting shorter and shorter.

Inappropriate extension of this period favors patent holders at the expense of the public interest in the earliest possible availability of generics.

(4) Limits on parallel importation. Once a patented product is placed on the market – in any country – the exclusive marketing right associated with the patent has been ‘exhausted’ and no longer restricts sale of the product elsewhere. International exhaustion of rights makes ‘parallel importation’ possible; this is the importation of a patented drug placed legitimately on the market elsewhere at a lower price. This practice permits countries to obtain cheaper patented medicines by taking advantage of lower prices in foreign markets for the exact same product. Yet the US-Singapore FTA ‘enhances the ability of patent owners to prohibit international exhaustion’ by requiring the U.S. and Singapore to institute measures that enable patent holders to block parallel importation into these two markets.³⁰ Since TRIPS leaves it to countries to

IFAC 3 report on US-Singapore FTA.

³⁰ IFAC 3 report on US-Singapore FTA. Under Article 16.7 of the US-Singapore FTA, the U.S. and Singapore must provide measures to patent holders that enable them to block parallel importation into the U.S. or Singapore, when medicines are imported in violation of a licensing contract abroad (for example, if the licensing contract is restricted to marketing a drug only in one country but the drug is then exported to the U.S. via parallel importation, the patent holder under this provision would have a cause of action against the importer in the US). This makes the U.S. and Singapore responsible for helping police private licensing contracts abroad for patent holders.

regulate parallel importation under their national laws, this provision is a case of 'TRIPS-plus'.³¹

Singapore is already bound by the TRIPS Agreement, so clearly the only rationale for including an IP chapter in this bilateral FTA is to ratchet up IP protections to TRIPS-plus levels in the interest of industry and to the detriment of access to medicines. Nearly all U.S. trading partners – and certainly all negotiating countries of the FTAA and other regional/bilateral FTAs currently under negotiation – are already subject to TRIPS obligations as WTO members. Because Singapore is a relatively rich country, the government and much of its population can afford branded drugs. Other countries that are negotiating FTAs with the United States are not in the same situation, so provisions that restrict their capacity to obtain generics will be particularly harmful to public health.

Central America Free Trade Agreement (CAFTA) and the Free Trade Area of the Americas (FTAA)

The negotiating text for CAFTA has not been made available to the public but, based on stated USTR aims in these negotiations, USTR has certainly tabled Singapore-style IP provisions. These Central American countries are being offered access to the largest market in the world, in exchange for accepting intellectual property provisions that will undermine their capacity to obtain affordable medicines for their citizens. This decision is extremely difficult and important: enhanced market access may offer new jobs and boost economic growth, but the right to health is a fundamental human right which should not be traded away. Unfortunately, health ministers are not involved in negotiations to weigh in on the negative impact of accepting TRIPS-plus measures.

Box 4 Guatemala's unilateral TRIPS-plus concessions

It is bad enough that USTR is pushing for TRIPS-plus provisions in CAFTA negotiations, but it is even worse that countries such as Guatemala are making IP concessions unilaterally. A developing country, it does not have to comply with TRIPS patent provisions until 2005. Given that 75 per cent of its population lives below the poverty line, with 58 per cent living in extreme

³¹ Consumers and lawmakers in the United States are exploring parallel importation of patented drugs from Canada to take advantage of the country's lower drug prices. While this practice is controversial and falls under a gray area of U.S. law, it is not illegal under TRIPS and could provide an important option for poor countries to access patented medicines at lower prices by importing them from other countries.

poverty, Guatemala cannot rely on expensive patented drugs to meet the healthcare needs of its population.

In 2002, after receiving USAID-funded legal advice, the Guatemalan Congress passed a law providing for fifteen years of protection for test data – three times the protection period provided under U.S. law. Under TRIPS, Guatemala is only required, by 2005, to introduce a measure to protect test data from ‘unfair commercial use’. The 2002 law goes much further than this and would prevent generic producers from relying on branded drug-test data to gain marketing approval, creating an obstacle to introduction of generic competition. The law also introduced patenting of pharmaceutical products, ahead of the 2005 TRIPS deadline. The Guatemalan Congress rejected this law, but then in April of 2003 introduced a different TRIPS-plus patent law – Decree 9-2003 – which provides five years of test data protection for registered originator drugs. Like the 2002 law, this decree prevents the government from relying on branded drug-test data when approving generic drugs during the five-year period.

Médecins Sans Frontières (Doctors Without Borders) has imported generic drugs for its work with AIDS patients in Guatemala, finding that generic medicines cost between 75 and 90 per cent less than branded drugs. 67,000 people in Guatemala are living with HIV/AIDS (Médecins Sans Frontières press release, 2003). Guatemala is unilaterally giving in to U.S. pressures for TRIPS-plus patent protection, even as it engages in CAFTA negotiations and could perhaps trade such concessions for better terms in the FTA.

In light of the health problems and poverty endemic to Central America, it is inappropriate and dangerous to include IP provisions in these trade negotiations that would limit access to generics. Central America has the second highest death rate from communicable diseases in Latin America, nearly 165,000 people are living with HIV/AIDS, and 30,000 cases of full-blown AIDS have been reported in the region.³² Resources for public health in Central America are extremely limited. Patented medicines sold at monopoly prices are too expensive for these countries to provide through their public health systems and too expensive for poor people to pay for out-of-pocket. The Costa Rican Pharmaceutical Industry has determined that implementation of TRIPS-plus patent rules would mean an increase in the cost of medicines of up to 800 per cent, since these rules would seriously restrict availability of cheap generics.³³ Generic competition is crucial to generating significant drops in drug prices, enabling more people to access treatment.

³² Pan-American Health Organization, ‘AIDS Surveillance in the Americas.’ June, 2002. (www.paho.org), and www.avert.org.

³³ La Prensa Gráfica, ‘Medicamentos dan dolor de cabeza a negociadore.’ February 28, 2003.

Examination of the draft negotiating text for the FTAA reveals that some proposals match the TRIPS-plus provisions in the Singapore agreement, which in turn match the stated aims of PhRMA. Even though the text does not identify which negotiating country is proposing the different bracketed proposals, these can clearly be identified as negotiating positions of the US. As with CAFTA, if the final FTAA text provides for TRIPS-plus patent protections, this will override the protections to public health provided in TRIPS and the Doha Declaration and the WTO deal on medicines. Oxfam believes that IP should be entirely excluded from all trade negotiations outside of the WTO.

Southern African Customs Union Free Trade Agreement (SACU)

The Bush administration has announced its intention to aggressively conclude a series of bilateral and regional free trade agreements, *'moving the world closer, step by step, towards the goal of comprehensive free trade'*.³⁴ As part of this plan, it aims to negotiate TRIPS-plus patent rules. The administration launched this agenda with Chile, Singapore, CAFTA, and FTAA negotiations. The FTA currently being negotiated with the Southern African Customs Union (SACU, composed of Botswana, Lesotho, Namibia, Swaziland, and South Africa) fits neatly into this agenda as well.

PhRMA has already issued stated goals for the SACU negotiations, its overall aim being to *'bring standards for IP protection into closer alignment with U.S. standards'*.³⁵ These include, predictably, full protection of test data, linkage between regulatory approval and patent status, limits on use of compulsory licensing, restrictions on parallel importation, and longer patent terms.³⁶ When the U.S. Trade Representative, Robert Zoellick, announced to Congress his intention to enter into an FTA with the SACU countries, he spoke of the administration's desire *'to establish (IP) standards that reflect a standard of protection similar to that found in U.S. law'*.³⁷

Apart from violating the spirit and intent of the Doha Declaration, USTR actions in this regard violate Executive Order 13155.³⁸ This

³⁴ USTR website.

³⁵ PhRMA 301 Submission, 2003.

³⁶ Ibid.

³⁷ Speech by Ambassador Zoellick, November 4, 2002.

³⁸ Set forth during Clinton administration, retained by Bush upon taking office. Specifically, it states: 'In administering sections 301-310 of the Trade Act of 1974, the United States shall not seek, through negotiations or otherwise, the revocation or revision of any intellectual property law or policy of a beneficiary sub-Saharan

Executive Order states that the United States will not undermine sub-Saharan African countries' efforts to obtain affordable medicines. The Executive Order refers to TRIPS-level provisions as providing adequate IPR protection, implying that there is no need to seek provisions that go beyond those patent rules. To achieve harmonization of SACU countries' IP standards with those in the U.S. under a free trade agreement, these sub-Saharan countries would have to adjust their patent laws to make them TRIPS-plus. The LDC members of SACU are not required to comply even with TRIPS until at least 2016, and they should not be coerced into implementing laws that increase drug prices, diminish access to generics, or otherwise benefit the multinational drug companies at the expense of their populations' health.

Sub-Saharan African countries are extremely poor and face enormous problems related to public health; it is estimated that 40 to 50 per cent of the population lives below the poverty line. Even in South Africa, which has a much higher per capita income than other African countries, more than 18 million people live below the poverty line.³⁹ This is largely due to unequal distribution of income; the poorest 20 per cent of income earners receive only 1.5 per cent of total income, while the top 10 per cent have 50 per cent of total income.⁴⁰ In a region already burdened by substantial poverty, the HIV/AIDS crisis is straining health budgets and hampering development. South Africa has an HIV prevalence rate of 26.5 per cent, and more than 600 people a day die of AIDS-related causes. Botswana has an HIV prevalence rate of 38 per cent. These countries will need to use available healthcare resources in the most cost-effective way possible to ensure treatment of the maximum number of AIDS patients.⁴¹

Efforts to enhance the rights of patent holders in the Southern African countries, which will lead to higher drug prices and therefore reduced access to treatment for African patients – most of whom are desperately poor and lack access to even the most basic life-saving medicines – are indefensible. Free trade agreements with the region should not limit availability of affordable medicines. As

African country, as determined by the President, that regulates HIV/AIDS pharmaceuticals or medical technologies.'

³⁹ Mayibuye May/June 1998, cited in 'Facing Poverty: Challenges and some churches' response in Southern Africa', Samuel M Silungwe. (http://web.uct.ac.za/depts/ricsa/sam_pr.htm).

⁴⁰ Silungwe.

⁴¹ 2002 data from www.avert.org website.

in other bilateral and regional trade talks, IP should be excluded from SACU negotiations, and the Southern African countries must retain the right to use the safeguards in TRIPS and the Doha Declaration. This is an issue of life or death for millions of people.

Bilateral bullying – ‘Special 301’

Under Section 301 of the Trade Act of 1974, USTR issues a yearly report threatening foreign countries with trade sanctions for not adequately protecting the intellectual property of U.S. companies. A country can be found to deny such protection even if it is in compliance with its TRIPS obligations. This means that USTR can threaten countries for not having TRIPS-plus provisions – for not having *exceeded* mere compliance with their international obligations. To compile the report, USTR consults with affected industry groups but not with healthcare or development advocates.

The threat of sanctions under Special 301, consisting of the withdrawal of concessions under the U.S. Generalized System of Preferences (GSP), is often enough to get trading partners to change their laws, regardless of the potential impact on public health. 301 is a big stick feared by developing countries, which are vulnerable to bilateral pressure because of the threat of trade sanctions and also because of the diplomatic and political pressures that such targeting implies. Despite U.S. endorsement of the Doha Declaration, bilateral bullying by USTR on behalf of the pharmaceutical industry continues. In 2002, USTR included 27 countries in its Special 301

report for concerns over intellectual property and pharmaceuticals. In the 2003 report 31 countries are targeted – all but one in the developing world.

Positively, the USTR refrained from targeting least-developed countries in the 2003 report. However, it targeted key generics-manufacturing countries, including India, Chile, Argentina, and Egypt, which have thriving generics industries that the U.S. pharmaceutical lobby would like to see thwarted. These countries could serve as suppliers to the world's poorest countries, which cannot manufacture affordable medicines for their citizens and where patented drugs are priced out of reach of most people. If coerced or pressured into instituting TRIPS-plus IP laws, they could be blocked from supplying poor countries with affordable medicines. Generics-producing countries are concentrated in the 'priority' and 'priority watch' country categories of the report, meaning that they are closer to being punished with sanctions than the other countries targeted.

The USTR report focuses on issues nearly identical to those emphasized in PhRMA's annual 301 submission to the U.S. government. For example, the top complaints in PhRMA's 2003 submission to USTR were protection of test data (37 countries cited), enforcement concerns (18), counterfeiting and trademark concerns (13), and lack of linkage between regulatory approval and patent term (20). The top complaints listed in the USTR report (ranked by number of complaints in each category) are these same complaints; these are also the key TRIPS-plus trade provisions sought by USTR in FTA negotiations.

Box 5 Argentina: victim of U.S. 301 bullying

Argentina has been facing a severe financial crisis since early 2002: 37 per cent of its population lives in poverty, and 25 per cent is unemployed. Despite the country's economic difficulties, the USTR refused to restore its trade preferences under the GSP program until outstanding complaints about Argentina's patent system were addressed. In 1997, the U.S. withdrew 50 per cent of the country's benefits under the GSP system, following placement of the country on the USTR 301 watch list for inadequate patent protections – even though Argentina was not required to comply with TRIPS until 2000.

In 1999, the U.S. initiated a case at the WTO against Argentina for failing to provide adequate protection for patents and test data, prior to the country's 2000 deadline for TRIPS compliance, and even though TRIPS only vaguely requires that test data be safeguarded against 'unfair commercial use'. Following consultations in Geneva, a bilateral council was set up so that the two countries could address this and other bilateral trade issues. But a bilateral council in which one party is threatening the other and withdrawing trade preferences constitutes bullying, not discussion, with loss of GSP being used as a stick. The U.S. and Argentina announced in April of 2002 that they had resolved certain aspects of the IP dispute, but Argentina has not acquiesced to U.S. demands for greater protection of test data.

The U.S. continues to hold Argentina's GSP status hostage to an agreement to institute TRIPS-plus patent protections, particularly of test data. The administration wrote this year that 'benefits will not be restored unless the concerns of the United States are addressed adequately', vaguely declaring itself 'committed to giving full consideration' to the country's request for expanded GSP market access (USTR 2003 annual trade review).

Despite the public and WTO focus on compulsory licensing as a key way of facilitating access to affordable medicines, PhRMA in 2003 targeted 14 countries for excessively broad compulsory licensing provisions. Due to public attention focused on the issue, USTR did not target countries under this category in its own report this year – although it continues to push for strict limitations on compulsory licensing in bilateral and regional trade negotiations.

Overall, the focus of PhRMA – and USTR on its behalf – appears to have shifted to the protection of test data, which is now the industry's key TRIPS-plus goal. The greatest number of complaints in USTR's 2003 report center on inadequate protection of test data, for which the U.S. targeted countries like Guatemala, a developing country with per capita income of only \$1700, which is not yet required to implement even TRIPS. Guatemala has just passed a TRIPS-plus data-protection law, perhaps in response to bilateral threats under 301 (see Box 4). As outlined above, the U.S. is also pushing for TRIPS-plus test data protection in bilateral and regional

FTA negotiations. Trade negotiations result in legally binding treaties and are a much more effective way for industry to achieve higher standards of IP protection than coercion and threats under Special 301, which may or may not intimidate targeted countries sufficiently to induce compliance with U.S. patent standards. Although Special 301 remains an important tool, the USTR and industry are relying primarily on trade negotiations to limit generic competition.

PhRMA's TRIPS-plus agenda

It is shocking to compare the USTR's stated aims in intellectual property negotiations of FTAs – including the FTA with Singapore, CAFTA, and the FTAA – with the stated aims of the pharmaceutical lobby. They are often identical, despite the fact that one is a government agency that has undertaken a political commitment to uphold public health and the other is an industry focused on short-term maximization of profits. Of course, government officials are charged with defending the interests of domestic constituents, including industry groups, but this should be done in a legal, non-coercive, and transparent manner which balances competing interests, including public health and the welfare of citizens both at home and abroad. Instead, regardless of commitments such as the Doha Declaration, key aspects of U.S. trade policy – which directly impacts on other areas of foreign policy and international relations – appear to be driven by PhRMA.

PhRMA represents the U.S. drug industry's interests vis-à-vis the U.S. and other governments; its membership includes major pharmaceutical companies, including GSK, Pfizer, Novartis, and Merck. Industry's overriding goal in international terms appears to be the elimination or limitation of generic competition, through strong patent protections at the WTO and in bilateral and regional free trade agreements.

PhRMA, which stands for the Pharmaceutical Research and Manufacturers of America, is influential in Washington policy circles. It has 625 lobbyists based in Washington DC and actively engaged with members of Congress, the White House, and Bush administration officials on domestic legislation, international trade rules, and U.S. trade policies related to patents. And because the industry overwhelmingly supports the Republican Party, the current administration may be even more aggressive than previous administrations in advancing its interests. In 2000, the industry

contributed approximately \$20,142,583 in campaign contributions, 76 per cent of which went to the Republican Party.⁴² In 2002, the industry gave \$29,371,406, with \$21,719,527 of that money going to Republicans.⁴³ In addition, it spends approximately \$120 million per year on lobbying. This is a drop in the ocean compared with its yearly sales: an estimated \$400 billion in 2002. The ten largest U.S. drug companies made \$35.9 billion in profit in 2002, with a rate of return for shareholders of 27.6 per cent, more than two and a half times the Fortune 500 average of 10.2 per cent.⁴⁴

In a 2001 report, Public Citizen revealed the following facts:

- The drug industry spent \$262 million on political influence in the 1999-2000 election cycle, including \$177 million on lobbying and \$20 million on campaign contributions. (In 2002, the industry increased its contributions to over \$29 million.)⁴⁵
- The cost of the industry's army of lobbyists in 2000 alone was \$92.3 million. Brand-name drug companies spent \$90.0 million on lobbying; generic drug companies spent \$2.3 million.⁴⁶

PhRMA is frequently successful in blocking both domestic and international health initiatives that would undermine its profits. In the Uruguay Round of trade talks (1986-1994), the group successfully lobbied USTR, which in turn pressured its trading partners, for conclusion of the TRIPS Agreement. Now, as evidenced in its submissions to the administration, comments as participants in advisory committees, and official testimony, PhRMA members are pressing USTR to seek harmonization of all countries' IP laws with those of the US, resulting in levels of patent protection that far exceed TRIPS standards. The industry clearly aims to ratchet up global patent protections to a new TRIPS-plus international standard, which would apply in developing countries where such stringent IP protection undermines access to medicines, is costly to implement, and conflicts with development goals, including availability of new products and technology. By locking

⁴² 'The Other Drug War: Big Pharma's 625 Washington Lobbyists', Public Citizen, 2001.

⁴³ www.opensecrets.org website.

⁴⁴ Public Citizen, June 2003. 'Drug Industry Profits 2002: Hefty Pharmaceutical Industry Margins Dwarf Other Industries.'

⁴⁵ www.opensecrets.org website.

⁴⁶ 'The Other Drug War: Big Pharma's 625 Washington Lobbyists', Public Citizen, 2001.

poor countries into TRIPS-plus patent obligations, industry aims to limit generic competition globally.

The following are the most often cited industry aims, all of which are TRIPS-plus: limits on use of compulsory licensing, enhanced test data protection, linkage of regulatory approval for generics to the patent status of the branded drug, and restrictions on parallel importation. The industry also seeks expanded enforcement of IP provisions, exceeding enforcement requirements under TRIPS. In addition, PhRMA has consistently urged USTR to pressure developing and least-developed countries to bring their laws into early compliance with TRIPS, even though these countries can and should take advantage of the transition period provided under WTO rules.

Comparison of the USTR agenda on patents with that of PhRMA makes clear why the U.S. has thwarted meaningful application of the Doha Declaration, despite having promised two years ago to prioritize global public health over patent rights. PhRMA, working through the U.S. government, is seeking to limit generic competition which lowers drug prices and undercuts its profits. U.S. TRIPS-plus negotiating positions on patents are generated by PhRMA, which then monitors their implementation around the world. And the United States is powerful enough to offer financial assistance and access to its markets – or threaten sanctions and diplomatic pressure – to obtain the strict patent protections sought by its pharmaceutical lobby. Sadly, the cost of pushing PhRMA's agenda will be paid by the millions of poor people whose health problems will go untreated if cheap generics are no longer available.

Conclusions and Oxfam recommendations

Despite its endorsement of the Doha Declaration on TRIPS and Public Health two years ago, the United States' trade policies and practices do not yet prioritize public health over patent rights. Oxfam's evaluation of the impact of U.S. trade policies on health and access to medicines was pessimistic last year, and in 2003 it is even more so. The U.S. is not only backtracking on Doha, but has been actively undermining the interests of patients in poor countries. By providing biased technical assistance, fighting pro-health amendment of TRIPS, negotiating TRIPS-plus provisions in bilateral and regional FTAs, and bullying countries bilaterally to institute high levels of patent protection, the U.S. is putting public health in developing and least-developed countries at risk. Sadly,

for the second year in a row, Oxfam finds that U.S. trade policies reflect the interests of Big Pharma, without taking into consideration how industry goals hurt patients in the developing world.

Oxfam makes the following recommendations:

- WTO members should ensure that the final TRIPS amendment, aimed at lifting restrictions on the export of affordable generic versions of new drugs to countries without drug-production capacity, is simplified. Unnecessary red tape should be removed, and there should be no mandatory limits on country eligibility or on the diseases for which such medicines can be procured, in keeping with the Doha Declaration. WTO member states should amend their legislation accordingly.
- The U.S. should stop using the threat of trade sanctions to bully countries into adopting 'TRIPS plus' intellectual property protections. TRIPS-plus rules further limit the availability of affordable generics in countries where they are urgently needed, and they contravene the Doha Declaration.
- The U.S. should also stop using its bilateral trade agreements such as CAFTA, regional agreements such as the FTAA, or negotiations over to WTO accession, to pressure developing and least-developed countries into adopting TRIPS-plus patent rules.
- The U.S. should provide technical assistance to developing countries that favors public health and access to affordable medicines, rather than the interests of the pharmaceutical industry.
- Developing countries should resist pressures to implement TRIPS-plus measures, and should make full use of the TRIPS flexibilities, including the recent WTO deal, in order to gain access to medicines in line with the Doha Declaration.
- The international community must continue to monitor the health impacts of the TRIPS Agreement, and should consider further future reforms to the Agreement in order to give developing countries greater freedom to decide the appropriate length and scope of patents protection for medicines based on public-health needs. More broadly, evidence from authoritative sources indicates the need for a substantive review of the entire TRIPS Agreement in the light of its detrimental impact on innovation, access to knowledge-based goods, and development.

'Intellectual property systems may, if we are not careful, introduce distortions that are detrimental to the interests of developing countries ... Higher IP standards should not be pressed on developing countries without a serious and objective assessment of their impact on development and poor people.'

We need to ensure that the global IP system evolves so that ... it contributes to the reduction of poverty in developing countries'.

(UK Commission on Intellectual Property Rights, 2002)

Annex

Special 301 Complaints: USTR, PhRMA

Table 1: Frequency of various complaints about intellectual property and pharmaceutical in the USTR Special 301 Reports for years 2002 and 2003

Complaint	USTR 2002	USTR 2003
Protection of test data	19	20
Enforcement concerns	9	13
Counterfeiting and trademark concerns	5	6
Lack of linkage between patent and regulatory authorities	2	4
Patent office backlogs	3	2
Long regulatory delays	2	2
No protection of second use patents	2	2
Exclusion of subject matter from patentability	1	1
Discrimination against fields of technology	1	0
Overly broad compulsory licensing provisions	1	0
No protection of product or process patents	2	0

Table 2: Countries cited by the USTR in the Special 301 Reports for each specific complaint dealing with pharmaceuticals

Complaint	Countries cited in 2002	Countries cited in 2003
Protection of test data	China, Argentina, Colombia, Dominican Republic, Egypt, Hungary, India, Israel, Bolivia, Canada, Chile, Costa Rica, Greece, Lithuania, Peru, Poland, Slovakia, Turkey, Venezuela	Argentina, India, Philippines, Poland, Bolivia, Canada, Colombia, Costa Rica, Croatia, Ecuador, Egypt, Guatemala, Hungary, Israel, Mexico, Pakistan, Peru, Slovakia, Turkey, Venezuela
Enforcement concerns	Argentina, Egypt, Hungary, Bolivia, Canada, Costa Rica, Korea, Saudi Arabia, Vietnam	China, Argentina, Philippines, Russia, Taiwan, Canada, Croatia, Ecuador, Mexico, Pakistan, Romania, Uruguay, Vietnam
Counterfeiting and trademark concerns	China, Philippines, Taiwan, Thailand, Venezuela	Paraguay, India, Philippines, Taiwan, Malaysia, Vietnam
Lack of linkage between patent and regulatory authorities	China, Korea	Chile, Croatia, Ecuador, Mexico
Patent office backlogs	Brazil, India, Chile	Brazil, Chile
Long regulatory delays	Chile, Pakistan	Croatia, Italy
No protection of second use patents	Colombia, Peru	Peru, Venezuela
Exclusion of subject matter from patentability	India	Guatemala
Discrimination against fields of technology	Egypt	-na-
Overly broad compulsory licensing provisions	India	-na-
No protection of product or process patents	India, Poland	-na-

Table 3: Number of countries cited for each of the various complaints by PhRMA in its submission to the USTR for its Special 301 Report in 2002 and 2003

Complaint	PhRMA 2002	PhRMA 2003
Protection of test data	34	37
Enforcement concerns	21	18
Counterfeiting and trademark concerns	11	13
Lack of linkage between patent and regulatory authorities	14	20
Patent office backlogs	4	5
Long regulatory delays	6	4
No protection of second use patents	7	10
Exclusion of subject matter from patentability	5	9
Discrimination against fields of technology	4	3
Overly broad compulsory licensing provisions	15	14
No protection of product or process patents	6	4

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