

Public Health at Risk

A US Free Trade Agreement could threaten access to medicines in Thailand

New stringent drug patent and marketing rules being negotiated in a Free Trade Agreement (FTA) between the US and Thailand would limit competition and reduce access to affordable medicines in Thailand. This would threaten the future of existing successful Thai HIV/AIDS treatment programmes, which rely on inexpensive generic drugs, and thus deprive thousands of people of effective treatment. Oxfam opposes an FTA with intellectual property rules that exceed the standards agreed at the World Trade Organization.

Glossary

ARV: antiretroviral drugs are medicines for the treatment of infection by retroviruses, primarily HIV. Different classes of antiretroviral drugs act at different stages of the HIV life cycle.

Baht: Thai currency: 38 baht is roughly equivalent to \$1.00, €0.80, and £0.55.

Compulsory license: a government measure that permits a patent to be overridden so that another party (public or private) can use the patent after paying reasonable compensation to the patent holder.

Fast Track: (also known as the Trade Promotion Authority or TPA). US legislation that authorizes the Executive branch to negotiate trade agreements and then bring them to Congress for a 'yes' or 'no' vote without any possibility to amend them.

FTA: Free Trade Agreement.

GPO: Government Pharmaceutical Organization, a state enterprise under the Ministry of Public Health in Thailand.

NAPHA: Thailand's National Access to Antiretroviral Program for People Living with HIV/AIDS.

NGO: Non-governmental organization.

Parallel importation: the importation of a patented drug from a third country where its market price is lower than that in the country of origin due to the differential pricing practice by drug companies.

RTA: Regional Trade Agreement.

TRIPS: Trade-Related Aspects of Intellectual Property Rights. The WTO TRIPS Agreement establishes minimum levels of protection that each government has to give to the intellectual property of other WTO members. The agreement was included in the 1986-1994 Uruguay Round global trade negotiations that concluded with the formation of the WTO. It applies to all members of the WTO.

WTO: World Trade Organization

Contents

Glossary	2
1 Introduction	6
2 HIV/AIDS in Thailand.....	7
3 The HIV/AIDS treatment program	8
4 Patent barriers to HIV/AIDS treatment.....	13
5 The problem with intellectual property provisions in the FTA16	
6 Rights and wrongs	20
7 Conclusion.....	22
8 Recommendations	23

Summary and recommendations

Even though the world faces the threat of potential new epidemics like avian influenza, the effects of trade rules on public health attract little attention. Governments recently reaffirmed their commitment to meet the Millennium Development Goals which include combating HIV/AIDS, malaria and other major diseases, yet little attention is given to the implications of United States Free Trade Agreements (US FTAs) with developing countries such as Thailand, for access to affordable medicines to treat those diseases. These FTAs do much more than regulate tariffs for cross-border trade in goods and services: they change the rules of intellectual property protection in ways that will undermine public health by limiting access to affordable medicines.

This report seeks to draw attention to the potential effect on access to medicines of new intellectual property rights protections in US FTAs. It is part of Oxfam's broader critique of trade rules in FTAs that have adverse effects on development and poverty reduction.¹

Thailand is a positive example of a developing country that has created effective programs to address the HIV/AIDS epidemic, having invested in prevention and treatment early on. More than 1 million women, men, and children have contracted HIV in Thailand and more than 500,000 people have died of AIDS since the outbreak of the epidemic. Thailand's prevention efforts, which helped avoid more than 5 million new infections, are widely recognized as a success story among developing countries. Nevertheless, there are still around 20,000 new infections each year, with half of new adult infections occurring among women.

By preventing a much larger epidemic, Thailand avoided much larger treatment costs. For every baht invested in prevention and treatment in the 1990s, Thailand saved 43 baht in added treatment costs. In 2000 the Ministry of Public Health created the National Access to Antiretroviral Program for People Living with HIV/AIDS (NAPHA), providing a wide range of triple-drug antiretroviral (ARV) therapy. Two years later, the Government Pharmaceutical Organization (GPO) began producing its first ARV triple drug 'cocktail' called GPO-vir for 1,200 baht (\$ 31) per patient per month, compared with 18,620 baht (\$ 490) for imported, brand-name drugs.

As a result of these efforts, the Thai government has been able to provide ARV drugs to increasing numbers of people who need them. The most important factor making this possible has been the government's ability to procure inexpensive generic drugs. With the introduction of GPO-vir, the HIV/AIDS treatment program was expanded more than eight-fold from 2001-2003 with only a 40 per cent increase in budget. Thanks to the availability of these generic medicines, the government is able to offer life-saving HIV/AIDS medicines to approximately 80,000 people, with plans to expand the program in coming years.

But as Thailand maintains and scales up treatment of people with HIV/AIDS, there is trouble on the horizon. Over time, increasing numbers of Thailand's population with HIV/AIDS will need access to 'second-line' ARVs, because viruses typically develop resistance to drugs after a period of time, and treatment with 'first-line' regimens will eventually fail. Local production of GPO-vir is legal because these first-line drugs were invented before Thailand introduced patent protection for medicines in 1992 and, therefore, they could

not be patented in the country. However, second-line therapies were developed more recently and are patented in Thailand, where they cost, on average, 14 times more than first-line treatments.

Thus, the future of treatment program in Thailand could be threatened if the United States succeeds in pressuring the Thai government to accept stringent new drug patent and marketing rules during FTA negotiations. US pressure to strengthen intellectual property protection is not new in Thailand: it dates back 20 years and includes denying trade preferences under the US General System of Preferences in 1989 and 1991. Facing intense pressure, Thailand amended its existing patent law in 1992 to allow patents on pharmaceuticals, and extended patent life from 15 to 20 years. The law was amended again in 1999 to comply with the WTO Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS).

As permitted by TRIPS, the Thai patent law currently allows flexibilities that help lower the price of medicines, such as compulsory licensing, which allows the government to override a patent to meet public health needs. According to a recent World Bank report, '...by exercising compulsory licensing to reduce the cost of second-line therapy by 90 per cent, the Royal Thai Government would reduce its future budgetary obligations by 3.2 billion discounted dollars (127 billion discounted baht) through the year 2025.'

But it is likely that provisions in a US-Thailand FTA would limit the government's flexibility to issue compulsory licenses, and would create a number of other obstacles to production and marketing of generic drugs. These new intellectual property rules exceed Thailand's obligations under TRIPS and could undermine the country's ability to provide affordable ARVs and other medicines to its population.

The US proposal on intellectual property rights for medicines in the US-Thailand FTA includes provisions similar to those in other US FTAs. In some cases, provisions are stronger than in most previous agreements and include, for example, extension of the patent term, protection of test data, and linkage between marketing approval and patent status. Additional provisions that have been included in some previous US FTAs, such as restrictions on the grounds for compulsory licensing, expansion of the patent scope, and limits to challenging potentially invalid patents, will further limit the use of important existing flexibilities in drug patent and marketing rules. The incorporation of these so-called 'TRIPS-plus' rules into this FTA could seriously hamper Thailand's HIV/AIDS programs, thus depriving thousands of people of effective treatment.

Oxfam recommends that no intellectual property provisions beyond the commitments established in TRIPS be included in any trade agreement between the United States and developing countries, such as Thailand.

US-Thailand FTA negotiations should be halted in order to carry out and take into account independent studies on the potential impact of proposed provisions on public health. Any future negotiations should involve greater transparency, including public disclosure of the negotiating text, and should take into account concerns and proposals of civil society stakeholders. In negotiating any trade agreement with the United States, Thailand should ensure that it can maintain and enact laws and create policies which uphold the right to public health and which promote broad access to safe, effective and affordable medicines. No trade agreement should negotiate away public health.

1 Introduction

'The effects of antiretroviral drugs are clear. They improve patients' lives and help them to resume their daily activities. Patients also have a better immune system and have better resistance to opportunistic diseases. This is obvious when patients walk in my office with a smile, having gained their weight back to normal. After taking antiretroviral drugs correctly and regularly, patients look well and are like any healthy men and women.'

(Dr. Janjira Jirtaknatee, physician)

Access to HIV/AIDS medicines makes a huge difference to the lives of infected people and their families. Not only do these medicines help people live longer, but they also greatly improve the quality of their lives, reduce the stigma and discrimination that they might experience, and enable them to contribute to the economic and social welfare of their families, their communities, and their countries as a whole. Thailand is a positive example of a developing country that has created effective HIV/AIDS treatment programs, with beneficial results for its population. It has a health-care system that can deliver antiretroviral (ARV) therapy and other treatments to those in need. Thanks to the availability of affordable generic medicines the government is able to offer life-saving HIV/AIDS medicines to approximately 80,000 people,² with plans to expand the program in coming years.

Thai programs to provide medicines for people with HIV/AIDS rely on inexpensive drugs. However, the future of treatment programs in Thailand could be threatened if the United States succeeds in pressuring Thailand to accept stringent new drug patent and marketing rules under a bilateral Free Trade Agreement (FTA). These new rules could undermine the ability of Thailand to provide affordable medicines to its population.

Negotiations for a FTA were launched in June of 2004, and have proceeded slowly for the last two years. In nine other FTA negotiations completed in the last four years, the US has consistently – and successfully – pressured other countries to accept new, strict intellectual property rules which can seriously obstruct efforts to lower the price and increase the accessibility of life-saving medicines. These new rules exceed the standards incorporated in the WTO Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) and:

- prevent or delay the introduction of affordable generic medicines, by restricting or limiting the use of public health safeguards in the TRIPS Agreement; and

- undermine the implementation of the 2001 WTO Doha Declaration on TRIPS and Public Health that reconfirmed the primacy of public health over private patents.

The incorporation of such 'TRIPS-plus' standards into the US-Thailand FTA could seriously hamper Thailand's HIV/AIDS programs by depriving thousands of people of effective treatment. Oxfam believes the United States should support the long-term sustainability of Thailand's HIV/AIDS programs, rather than undermine it by seeking stronger intellectual property standards through backdoor restrictions in the US-Thailand FTA.

While this paper focuses on the issue of HIV/AIDS treatment in Thailand, it is important to note that the harmful impact of stricter intellectual property rules applies to a much broader range of diseases and treatments including opportunistic infections which frequently afflict people living with HIV/AIDS, other infectious diseases, and chronic illnesses such as heart disease and cancer.

2 HIV/AIDS in Thailand

More than 1 million women, men, and children have contracted HIV in Thailand, and more than 500,000 have died of AIDS since the outbreak of the epidemic. In spite of successful prevention efforts, there are still around 20,000 new infections each year.³

Widespread transmission of HIV in Thailand occurred in the late 1980s. Between 1988 and 1989, the rapid transmission of HIV was apparent among injecting drug-users who showed over 50 per cent HIV prevalence in some provinces. From 1993 to 1997, 8,325 cases were reported, but it is believed that HIV infections spread most rapidly among sex workers. Nearly half the sex workers in Chiang Mai, a northern province of Thailand, were infected with HIV.⁴ The high rate of infection among female sex workers led to the rapid transmission of HIV/AIDS to their male clients, and from infected males to their wives, partners and children.

Aggressive prevention efforts have helped to slow the spread of the disease and it is estimated that more than 5 million infections have been prevented as a result.⁵ Nevertheless, there is evidence that infections are growing in the general population and among specific groups. For example, the rate of HIV infections among teenagers rose from 11 per cent in 2001 to 17 per cent the following year.⁶

Women have been heavily affected by the pandemic. At the early stage of the pandemic, around one-third of adults living with HIV/AIDS in Thailand were women, often infected by husbands or

partners who had become infected by the virus during commercial sex. While most HIV transmission in Thailand in the early 1990s occurred between sex workers and their clients, around 50 per cent of new infections were taking place between spouses ten years later.⁷

Half of new adult infections are now occurring among women. The current figure shows that 70 per cent of young people between the ages of 15 and 24 who are living with HIV/AIDS are female.⁸ The rate of HIV infection among pregnant women is relatively high but variable. From 0.5 per cent in 1990, HIV prevalence among pregnant women increased to 2.4 per cent in 1995, but decreased to 1.18 and 1.09 in 2003 and 2004 respectively.⁹

In addition to the direct impact of HIV/AIDS, women often face a disproportionate burden of caring for sick family members or younger siblings, thus restricting employment or educational opportunities. In many cases, girls are much more likely to be withdrawn from school to perform caretaking tasks.

In recent years, the Thai government has taken important steps to contain the epidemic through the introduction of a strong prevention program which promotes condom use, provides medicines to prevent mother-to-child transmission, and provides a treatment program. With relatively successful programs, Thailand has contained the spread of the disease, and HIV prevalence has been progressively reduced. By preventing a much larger epidemic, Thailand has avoided much larger treatment costs. For every baht invested in prevention and treatment in the 1990s, Thailand saved 43 baht in added treatment costs.¹⁰ Thailand's prevention efforts are widely recognized as a success among developing countries.¹¹

3 The HIV/AIDS treatment program

'The treatment of people living with HIV/AIDS has come a long way. There is an increase in the variety of ARV drugs available in Thailand, particularly the local-made ARV drugs. Success of HIV treatment will occur if patients have access to medicine... The increased price of ARV drugs will have a major impact on people who buy ARV drugs by themselves. It will also affect the government's budget on health care schemes. We have to see the new policy that the government will create if there is a significant increase in the price of ARV drugs.'

(Waravhuti Kowatcharakul, physician)

Thailand's initial policy response to HIV/AIDS focused primarily on preventing the spread of the epidemic. Medical treatment was provided for the prevention of opportunistic infections only. No ARV

treatment was provided to HIV-related patients in the early stages of the HIV/AIDS campaign.

The Thai government subsequently realized that while preventing new HIV infections was crucial, a treatment program was also needed for those who had already contracted the virus. In 1992, the Thai Ministry of Public Health started to subsidize a treatment program of ARV drugs for a small number of people with HIV/AIDS. At the beginning, mono-ARV therapies involving *zidovudine* (AZT) were provided. These therapies proved to be inefficient and ineffective as the virus tended to mutate and become resistant to the medication. In 1995, the Ministry of Public Health switched to dual therapy using a combination of two ARV drugs and two years later to triple-drug therapy using a combination of three ARVs.

In 2000, the Thai Ministry of Public Health initiated the 'Access to Care' (ATC) pilot program to evaluate the feasibility of the administration of free ARV treatment to a group of 630 HIV-infected patients in six northern provinces with the highest number of AIDS cases. The objectives were to identify critical issues for implementation prior to further expansion of the program.¹²

From 2001-2003, the ATC pilot program developed into the 'National Access to Antiretroviral Program for People Living with HIV/AIDS' (NAPHA), which provided a wide range of triple-drug ARV therapy. Under this program, around 400 public hospitals began dispensing ARV drugs. Beneficiaries are selected by local committees comprising government officials, health workers and NGO representatives. The committees base decisions on medical assessments of HIV-infected patients to determine whether they meet the treatment criteria (for example, patients with a depressed immune system) set out in the guidelines developed by the national committee. Patients selected by the committee receive ARV drugs free of charge. These drugs are allocated to local hospitals throughout the country on a quota system. Small state-funded hospitals receive ARV drugs for 20 people at a time, while larger hospitals receive a quota of drugs for 40 people.

In 2002, the Thai government initiated a national health insurance system which covers 95 per cent of the population. The health insurance system provides basic health insurance for a fee of 30 baht (\$ 0.79) per visit to a clinic.¹³ The '30 baht' system did not initially cover ARV treatment, due to the high cost of drugs and limited public budgets. Although in October 2005 the government announced it would include ARV treatment in the '30 baht' scheme, the principles and ways to implement the system are still under discussion.

Despite obstacles, the Thai government has been able to provide ARV drugs to increasing numbers of people. This is partly due to increased

budget allocations for ARV treatment: the 2004 ARV budget grew to 800 million baht from 300 million baht in 2003.¹⁴ But the most important factor has been the ability of the government to procure inexpensive generic drugs.

Initially, Thailand's drug treatment program distributed branded drugs which cost more than 380,000 baht (\$ 10,000) per person per year. These prices were far beyond the government's limited budget. In 2002, the Government Pharmaceutical Organization (GPO), a state enterprise under the Ministry of Public Health, successfully produced its first ARV 'cocktail' called GPO-vir. GPO-vir, a fixed-dose combination of three drugs (*stavudine*, *lamivudine* and *nevirapine*) has become a cheap and affordable ARV treatment for many people with HIV/AIDS in Thailand. GPO-vir costs 1,200 baht (\$ 31) per patient per month compared to 18,620 baht (\$ 490) per patient per month for imported, brand-name drugs.

Between 2001 and 2003 the HIV-treatment program expanded more than eight-fold with only a 40 per cent increase in budget. The number of people on ARV treatment reached 50,000 at the end of 2004, and is approximately 80,000 today.¹⁵

'In early 2004, I had pneumonia and high fever and I was constantly in and out of the hospital. In June 2005, I had a CD4 check and a blood test and found that I am HIV positive. I quit my job at a department store because I was too weak to work. I felt really weak but my family and my husband gave me hope to live on, so I fight with the disease. Since October 2005, I have taken GPO-vir from the 30-Baht scheme. I don't know how much the ARV drugs cost because it's paid by the government. I will not be able to afford it if I have to pay for them by myself. The only income we have – 5,000 Baht (\$ 125) a month – is from my husband who helps his mother to repair shoes. He's also HIV positive, and one day, he will also have to take ARV drugs. It will be impossible to pay the drug bills for both of us by ourselves. Now, the scars are fading and my skin looks healthier. I no longer itch too. I also gained my weight back and may gain a little bit more. When I fully recover, I will find some light work.'

(Ratcharapa, 25, member of a local network of people living with HIV/AIDS in Chiang Mai Province)

Local generic production of these HIV/AIDS medicines is legal because these drugs were invented before Thailand introduced product-patent protection in 1992. Therefore, they could not be patented in the country.

However, procurement of other HIV/AIDS drugs has been hampered by the fact that they were patented in Thailand after 1992. Merck's *efavirenz* is one of those drugs. For drugs under patent, the government cannot legally import or produce generic versions

without using a compulsory license to override the patent (this is permitted under WTO TRIPS rules). Access to treatment regimes other than the standard 'first line' ARVs is important. For example, some people develop adverse reactions to *nevirapine* (one of the components in the Thai government's generic triple drug therapy), including liver and kidney damage, so they need to be given alternative drugs such as Merck's *efavirenz*. However, *efavirenz* is patented and is more expensive, nearly doubling the daily cost of HIV/AIDS medicines from 40 to 75 baht. Yet the Thai government, through NAPHA, provides this drug for patients who cannot tolerate *nevirapine*, adding further financial strain on the national health budget.

Furthermore, ARV medicines are only part of effective treatment for HIV/AIDS. While ARV treatment reduces the incidence of opportunistic infections, treating those infections directly can also save patients' lives and reduce the number of hospitalizations. Thailand is able to provide treatment for cryptococcal meningitis, a fatal opportunistic infection, because it can produce a cheap generic version of *fluconazole*, a drug developed by Pfizer for which the patent has expired. But certain other medicines vital for the treatment of other opportunistic infections are still under patent in Thailand and, therefore, too expensive to be used as part of the government program. For example, Roche's *ganciclovir* is needed to treat cytomegalovirus (CMV), a dangerous infection which can cause blindness and death, but because it is patented it is too expensive (2,854 Baht or \$ 75 per 500mg vial) to be included in the government's program.

While providing drug treatments is not a complete solution to the problems posed by HIV/AIDS, there is little doubt that they provide huge benefits to people living with HIV/AIDS and to society more generally. Drug therapies permit people with HIV/AIDS to support their families and communities; parents' lives can be prolonged and livelihoods maintained. In addition, ARV treatment reduces the discrimination and stigma associated with HIV/AIDS, and creates an incentive for HIV testing, which enhances AIDS prevention and control efforts.

However, as Thailand scales up and maintains treatment of people with HIV/AIDS, there is trouble on the horizon. In addition to its current first-line treatments, Thailand will need access to 'second-line' and 'third-line' treatments. This is inevitable as viruses typically develop resistance to drugs after a period of time. According to the World Health Organization's guidelines, treatment with first-line regimens will eventually fail and will require a second-line regimen to

be used. Over time, increasing numbers of Thailand's population with HIV/AIDS will need access to second-line ARVs.

These second-line therapies were, however, developed more recently and are patented in Thailand, meaning that they cost too much for government programs and are unaffordable for most patients. The World Health Organization recommends seven drugs as second-line treatments, including *lopinavir* which is patented in Thailand and is very expensive. A bottle of *lopinavir* syrup costs 11,770 Baht (\$ 310). A *lopinavir-ritonavir* combination costs 17,762 baht (\$ 467) per 180 capsules. The same drug combination is sold by an Indian generic company for 5,930 baht (\$ 156), but cannot be imported into Thailand because of patent restrictions. Of the seven WHO-recommended second-line ARVs, five are currently patented or could become patented in Thailand in the near future.¹⁶

'If people living with HIV/AIDS have no access to the second line ARV drugs, those who have developed resistance to their first line ARV drugs will no longer benefit from their treatments. Also there is the possibility that new cases will be infected with resistant viruses and will need to be treated with second line drugs, most of which are still under patent and cannot be made locally.'

(Suwalai Chalermpanmetagul, registered nurse with the Program for HIV Prevention and Treatment in Chiang Mai province)

'We have won the first battle by reducing the price of the first line drug. We have to win another battle in reducing the price of second line ARV drugs.'

(Dr. Sophie Le Coeur, physician with the Program for HIV Prevention and Treatment in Chiang Mai province)

There is no guarantee that Thailand will have the budget to fund new medicines in the future. External shocks and many other factors can play havoc with government finances. For example, the 1997 economic crisis had strong negative consequences on government programs, and resulted in a significant reduction and reorientation in the budget for HIV/AIDS prevention and treatment. Between 1996 and 2002, Thailand's spending declined from 1,419 million baht (\$ 37.3 million) to 1,099 million baht (\$ 28.9 million)¹⁷ for HIV/AIDS medical interventions, including ARV drugs and drugs for treatment of opportunistic infections.

New stringent drug patent and marketing rules in a US FTA may mean that second-line drugs and future innovations will be available only to those who can afford the high prices associated with patented products. The higher cost of second-line therapies and other patented drugs may mean Thailand's treatment program will fail to sustain the lives of people with HIV/AIDS in the longer term.

4 Patent barriers to HIV/AIDS treatment

Various factors limit HIV/AIDS treatment in Thailand, including insufficient financing for health services. But patents are a significant obstacle to treatment, and their impact is likely to get worse if the Thai government signs an FTA with the US government containing 'TRIPS-plus' intellectual property rules.

The big pharmaceutical companies argue that increased levels of intellectual property protection are necessary in order to generate revenues to finance research and development (R&D). Yet according to their 2004 financial reports, the seven largest US pharmaceutical companies spend, on average, only 14 per cent of their revenues on R&D while 32 per cent is spent on marketing, advertising and administration. They report more in profits - 18 per cent of revenue - than they spend on R&D.¹⁸ Moreover, much of the research conducted by the pharmaceutical industry is in pursuit of higher-priced versions of existing medicines ('me too' drugs) or monopoly extensions for new uses of old drugs. For example, only 15 per cent of the new drug applications approved by the US Food and Drug Administration between 1989 and 2000 contained new molecular entities and were considered likely to provide clinical improvement over other products on the market.¹⁹

In fact, much of the research conducted by the pharmaceutical industry utilizes initial research funded by the US government, which invests nearly as much in R&D as the industry.²⁰ The government also subsidizes industry investment in research by making R&D expenditures tax-deductible (the corporate tax rate is about 34 per cent). For medicines needed in both rich and poor countries, such as antiretrovirals, companies recoup their expenses in the profitable market in developed countries. Developing countries in Asia, Africa and Latin America together account for only about 11 per cent of the world pharmaceutical market.²¹ There is little private research into health problems specific to developing countries because they are not lucrative markets. Research into HIV vaccines was ignored by companies until public institutions increased their investment. Thus, the social contract implicit in establishing patent rights - consumers pay more for medicines for a limited period, but benefit from innovation in return - does not apply in most of the developing world.

Since 1985, as a result of complaints by the Pharmaceutical Research and Manufacturers Association of America (PhRMA) claiming that weak patent protection was costing them millions of dollars in lost revenue, the Office of the United States Trade Representative (USTR) has pressured Thailand to strengthen its patent laws. As a result of these complaints, US trade preferences under the General System of

Preferences (GSP) were denied to imports from Thailand in 1989 and 1991. Facing intense pressure, Thailand amended its existing patent laws in 1992 to allow patents on pharmaceuticals, and extended patent life from 15 to 20 years. The law was amended again in 1999 to comply with obligations under the WTO TRIPS agreement.

Now, Thailand and most other WTO members must comply with the provisions related to medicines in the TRIPS agreement; Least Developed Countries have until 2016 to comply. Thus Thailand has forfeited the possibility of producing or importing cheap generic versions of patented medicines, except under a compulsory license.

As permitted by TRIPS, the Thai patent law currently allows flexibilities that help lower the price of medicines, such as compulsory licensing and parallel importation. Even though compulsory licenses are rarely invoked, their use remains an important policy tool for governments – and the threat of issuing such a license often serves as bargaining leverage in negotiations with pharmaceutical companies to induce them to reduce their prices. For example, in 2001, Canada threatened to issue a compulsory license for a supply of the antibiotic *Cipro* to respond to an anthrax scare. Eventually, Bayer, the maker of *Cipro*, agreed to provide the drug at discounted prices.²² And in October 2005, US Senator Charles Schumer threatened to push for a compulsory license on the avian influenza drug, *Tamiflu*, if its patent holder, Roche, did not agree to allow generics companies to produce the drug in order to increase its supply. Roche entered negotiations and reached agreement with several generics producers shortly thereafter.²³

Despite pressure from Thai civil society, the Thai government has not so far used these TRIPS ‘flexibilities’. However, it may need to do so in the future as the cost of its treatment programs rise. According to a recent World Bank report, ‘by exercising compulsory licensing to reduce the cost of second-line therapy by 90%, the Royal Thai Government would reduce its future budgetary obligations by 3.2 billion discounted dollars (127 billion discounted baht) through the year 2025 and cut by more than half the cost per life-year saved of the National Access to Antiretroviral Program for People Living with HIV/AIDS, from \$2,145 to \$940 per life year saved.’²⁴

However, provisions in a US-Thailand FTA are likely to limit the government’s flexibility to issue compulsory licenses and would create a number of other obstacles to production and marketing of generic drugs. Furthermore, it could become more difficult to challenge the validity of a patent. Thai civil society organizations have recently managed to use alternative legal means to revoke invalid HIV/AIDS patents on the ARV *didanosine* (ddI) (see box).

Thai civil society organizations successfully challenge invalid HIV/AIDS patents²⁵

Thai civil society organizations, particularly public health groups and organizations of people living with HIV/AIDS, have been key to Thailand's successful response to the epidemic. Their mobilization and advocacy has had a huge impact on implementing the commitment to treat people with HIV/AIDS and provide ARV medicines.

In addition, these organizations have been active in debates on patent law and public health. In 2002, through a series of court cases, the AIDS Access Foundation and the Foundation for Consumers and AIDS Patients successfully challenged Bristol-Myers Squibb's (BMS) patent for an improved formulation of *ddl*, an important anti-retroviral. This drug was originally patented in the US in 1989, before Thailand passed legislation that established patent protection for pharmaceutical products. Once the Thai patent law was in effect, BMS filed a patent application in Thailand for a formulation of the drug that would be easier to use and have fewer side effects. Then before the patent was granted, BMS amended its application to expand the patent scope to all drug strengths.

These civil society groups, joined by people living with HIV/AIDS, argued first that the granting of the patent was illegal because its scope had been unlawfully widened. They won the case, and in the process established an important precedent to give legal standing to consumers as plaintiffs in drug patent cases.

But BMS appealed, and civil society groups brought a new case charging that the patent did not meet the criteria of being new and involving an inventive step. During the court proceedings, BMS decided to terminate the case by renouncing this patent in Thailand. This has allowed the Thai government to begin generic manufacturing of *ddl* tablets.

The case of *ddl* illustrates how drug companies can attempt to use the patent law to extend the scope of their patent inappropriately. There is a danger that the possibility of similar challenges to patent abuse will be curtailed under the new US-Thailand FTA.

The key to reducing drug prices is to create competition among producers. Patents afford drug producers monopolistic control over production and prices. The most effective way to reduce prices and increase access is to promote generic competition. The current price differences between generic and patented drugs in Thailand suggest that the prices of vital patented drugs for alternative first-line and second-line treatment, along with medicines for treatment of opportunistic infections, could be as much as ten times higher than prices with generic competition. As increasing numbers of people with HIV/AIDS are switched from first-line to patented second-line treatments, the costs will skyrocket. Average cost for first-line treatments is 19,271 baht (\$ 482) annually, while the average cost for second-line treatments is 269,496 baht (\$ 6,737).²⁶

The story of a female patient in Chiang Mai

Noi found out she was HIV positive in 1995 when she was pregnant. Fortunately her baby was not infected.

'I suffered pneumonia, among other opportunistic diseases, and I went to a hospital for treatment. In 2002, the doctor prescribed ARV drugs (GPO-vir) for me, and luckily, my medical bill was covered by the national health care scheme. In 2004, I switched to a second-line drug, which was also made available through the healthcare scheme. Today I work with the network of People Living with HIV/AIDS (PLWHA), campaigning and speaking to people about the impacts of the FTA to the public.'

'I strongly disagree with the current US-Thailand FTA deal. I want the Thai government to call off the deal because the US government not only monopolizes the Thai medicine market, but also insists that the Thai government extend drug patents beyond 20 years. The outcome is that medicine will be a lot more expensive for all. The national healthcare scheme (30 Baht) does not have enough money in its budget to cover the patented second and third line ARV drugs. If the price of ARV drugs increases, the national health care scheme will collapse. Hundreds of thousands of people living with HIV/AIDS who need these drugs to survive will be greatly affected.'

'The US-Thailand FTA deal will allow US pharmaceutical companies to be able to make modifications to existing drugs by adding an extra substance or medicine combination and re-register the drugs as newly patented drugs. The result is that the patent will never expire and we will not be able to produce generic drugs here locally.'

'There's more. When there is a crisis in developing and underdeveloped countries, governments could claim their right to compulsory licensing and produce patented drugs locally as generics or importing cheap generic drugs from other countries. Under the US-Thailand FTA, this right will be obstructed or even eliminated.'

5 The problem with intellectual property provisions in the FTA

"...We will seek to include provisions that bring Thailand's intellectual property and customs regimes up to the standards set in our other recent FTAs..." (United States Trade Representative, February 12, 2004)

Intellectual property rights provisions first entered the formal negotiations between Thailand and the United States in January 2006. There are strong reasons to be concerned about the impact a final agreement may have on access to medicines in Thailand. First, a pattern has been established in recent FTAs negotiated by the United States whereby more stringent patent and drug-marketing rules are imposed – rules that go far beyond those of the WTO TRIPS. Secondly, secret, leaked information²⁷ indicates that the US-Thailand

FTA may go beyond other FTAs in several areas by restricting important existing flexibilities in the drug patent and marketing rules.

The intellectual property standards in recent US FTAs completed with developing countries exceed the obligations set by the WTO TRIPS agreement. They also contradict the 2001 WTO Doha Declaration on TRIPS and Public Health which affirmed the rights of governments 'to use to the full, the provisions in the TRIPS Agreement which provide flexibility' to 'protect public health and promote access to medicines for all.' Moreover, including these intellectual property provisions in FTAs contravenes US law: the Trade Promotion Authority Act (TPA) passed by US Congress in 2002 mandates the United States Trade Representative (USTR) 'to respect the [Doha] Declaration on the TRIPS Agreement and Public Health.'²⁸

All US-FTAs completed since US Congress passed the TPA in 2002 include the following 'TRIPS-plus' provisions:

- **Longer patent terms.** FTA provisions require governments to extend patent protection beyond the maximum 20-year period established under TRIPS to take account of delays in granting the patent or granting marketing approval. Extending this monopoly period will further delay the introduction of affordable generic medicines.
- **Data exclusivity.** FTAs create a new system of monopoly power, separate from patents, by blocking the registration (i.e. marketing approval) of generic medicines for at least 5 years, and possibly 10 years or more. TRIPS merely protects 'undisclosed data' from clinical trials generated by brand-name companies against 'unfair commercial use;' it mandates no monopoly period. Yet FTA provisions prevent drug regulatory authorities from relying on that data to grant marketing approval to a generic drug that has already been shown to be equivalent to the brand-name drug.

This will delay or prevent generic competition, even in the absence of patent barriers. Unable to rely on the originator company's data, generics producers would have to repeat unnecessary, time-consuming and costly clinical trials in order to prove the safety and efficacy of their drug to obtain marketing approval. Generics companies, which operate on small margins, would be unlikely to do so. In addition, repeating such tests may be unethical because they require people in the control group to take a placebo, even if they have a life-threatening illness and even though an effective drug is known. Furthermore, issuing a compulsory license would be rendered an unviable policy tool, as no authorized generic product would be able to enter the market in a timely way because the compulsory license would not override the data protection.²⁹

- **Linkage between marketing approval and patent status.** New provisions in FTAs prevent national drug regulatory authorities from registering generic versions of drugs until after the patent has expired. Regulatory authorities, which verify a drug's safety and efficacy, must thus become 'patent police' as the burden of enforcing private property rights is shifted from the patent owner to the state's regulatory authority. These provisions also prevent the effective use of compulsory licensing, because no generic drug could obtain marketing approval during the patent term, and in this way they delay the availability of affordable generic versions of new medicines until well after the expiry of a patent.

The USTR proposal on patents and related protections for medicines was leaked following the initial discussion on this issue at the negotiating session held between 9 and 13 January 2006 in Chiang Mai, Thailand. A review of the proposed text reveals that the provisions mentioned above are included, in some cases in a more restrictive manner than in most previous US FTAs. Furthermore, the proposal includes several provisions that have been excluded in most previous US FTAs.

Oxfam is very concerned about the potential impact of such new and stringent provisions in Thailand in light of the importance of generic medicines to the nearly universal health care system. The effect of the provisions on people living with HIV/AIDS is of particular concern.

The following analysis of the proposed provisions provides details of our concerns.

- **Patent term extension.** The patent term would be extended, with no upper limit such as that which exists in US law for 'unreasonable' delays in granting the patent or granting marketing approval. Unlike earlier FTAs, for example that with Singapore or the Central America Free Trade Agreement (CAFTA), the US-Thailand FTA would extend the effective patent term to take account of delays both in the US and in Thailand.
- **Data exclusivity.** There are several ways in which provisions granting protection for clinical trial data (which parallels the patent system) are designed to enhance the monopolies of brand-name pharmaceutical companies. As a result, they will prevent the marketing of generic drugs under a compulsory license and even in the absence of a patent.
 - Unlike the provisions of CAFTA, the scope of the data protected is broadened to cover all 'information' and not only 'undisclosed data.' Thus, even clinical trials published in US scientific journals could not be used by the Thai

regulatory authority, as it often does now, to register a generic drug.

- Data must be protected for all pharmaceutical products that are introduced in Thailand, not only for new innovative drugs. Data protection applies even if the product is on the market in the US or other countries, and even if the product is simply a combination of chemical entities already available in Thailand.
- The proposed period of protection is 'at least five years' starting from the date of marketing approval in each country. This goes beyond the maximum of five years required under US law. For Thailand, this could amount to almost 10 years of protection if the pharmaceutical company seeking marketing approval waits until its five years of protection in the US is about to expire before registering its drug in Thailand.
- Three additional years of monopoly protection are granted to the company of origin if it finds a new clinical use for a drug already on the market in some form and if new clinical trials are needed to gain marketing approval for the new use (for example, use by children). This requirement goes beyond the US FTAs with Singapore, the Andean countries and Central America.
- **Linkage.** Thailand's drug regulatory authority would become the 'patent police' to protect patent holders. It would be required to investigate and confirm that there are no existing patent claims implicated in a new generic product. If any claims exist, valid or not, Thailand would have to deny marketing approval. The regulatory authority would also have to notify the patent holder directly of the identity of the potential infringing registration.
- **Restrictions on the grounds for compulsory licensing.** These provisions would strictly limit Thailand's use of this important TRIPS safeguard that allows a government to override a patent, without any restrictions of the grounds upon which it can grant such a license, as long as the patent holder is given 'adequate' compensation. Unlike CAFTA or other US FTAs, these provisions would limit the use of a compulsory license only to remedy anti-competitive practices, for public non-commercial use, for a 'national emergency' or in a case of 'extreme urgency.' For the latter purposes, there would be limits on private sector use of the license and the patent holder would not be required to disclose information or technical know-how regarding the patent, all of which may delay or render its use ineffective. Such restrictions

could undermine the government's ability to bargain for cheaper patented drugs or to promote competition by generic producers which could reduce prices and increase access to medicines.

- **Expansion of patent scope.** Unlike FTAs with Singapore or Central America, a new provision would require granting patents for new uses or new methods of using an existing known product.³⁰ This would allow pharmaceutical companies to engage in deliberate strategies to prolong indefinitely or 'evergreen' their monopolies by granting additional 20-year patents for new therapeutic uses of old drugs, without any requirement for innovation.
- **Limits to challenging potentially invalid patents.** Unlike CAFTA, no challenges to patent validity would be permitted prior to granting the patent. Thai law currently allows for such legal procedures, which helps to avoid invalid granting of patents and delays to generic competition.³¹

Sathaporn, 36, an HIV/AIDS activist with the People Living with HIV/AIDS network (PLWHA)

'I learned about the effects of US-Thailand FTA from PLWHA. Information about the negative effects of the US-Thailand FTA, particularly on intellectual property rights, is not widely available to the public, so I joined the network to bring facts to people.'

'The intellectual property rights rules will not only affect us – people living with HIV/AIDS – but all patients and farmers. Access to ARV drugs will be very limited and drugs will be more expensive if the Thai government agrees with the deal on market-exclusivity and extension of patents on ARV drugs. The market exclusivity and patent extension should be removed from the negotiation.'

'The Thai government can trade with other countries, but don't let us suffer because this trade agreement involves the survival of people who need drugs for their treatment. The government must care for the well-being of Thais. I have to use medicine for the rest of my life and I will not be able to survive if the medicine is not available at a low price. My demand is not to be rich, but it's a demand for survival for people living with HIV/AIDS.'

6 Rights and wrongs

Patents are a legal creation. The patent system creates a 'property right' over knowledge in order to encourage people to invent and produce. Creators of knowledge have a legitimate interest in benefiting from their investment and labors. Because intellectual property is not physically tangible and can be used by many people simultaneously at no additional cost, a temporary monopoly license is required to prevent others from using it. But the system to protect

intellectual property rights exists for the sake of society, not for the enrichment of a few.

Patent and other intellectual property rights mechanisms offer legal monopolies in order to provide innovators with a return on their knowledge investment. The intention is to serve as an incentive for future innovation. The counter-balancing interest of society is in the proliferation of useful innovations. From an economic perspective, there is an inherent tension between monopoly rights and competition that leads to efficiency in the market. There is a trade-off between incentives for innovation, which the monopoly license is meant to provide, and competitive access to new technologies that benefit society. When it comes to medicines, however, the trade-off is in public health.

Thus, intellectual property rights with regard to medicines can come into conflict with other rights, notably the right to health. The right to health has been recognized as a fundamental human right, and is enshrined in a number of treaties, including the Constitution of the World Health Organization, the United Nations Charter,³² the Universal Declaration on Human Rights,³³ and the Convention on the Rights of the Child.³⁴ The most important human rights instrument that explicitly recognizes the right to health is the International Covenant on Economic, Social and Cultural Rights (ICESCR). Article 12 of the ICESCR creates a legally binding right to health, and Article 2 imposes legal obligations on all States parties to co-operate internationally to realize this right.

The right to health was defined as 'a right to the enjoyment of a variety of facilities, goods, services and conditions necessary for the realization of the highest attainable standard of health.' This includes 'a system of urgent medical care in cases of accidents, epidemics and similar health hazards,' as well as 'the provision of essential drugs' for prevalent diseases.³⁵ In April 2001, the 57th Session of the United Nations Commission on Human Rights adopted Resolution 2001/33, on 'Access to Medication in the Context of Pandemics such as HIV/AIDS', which confirmed that 'access to medication in the context of HIV/AIDS is one fundamental element for achieving progressively the full realization of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.'³⁶

Thailand ratified the ICESCR on 5 September 1999, and under Article 12 it has an obligation to make sure that its people have access to pharmaceuticals and healthcare services. The right to health under international law is guaranteed by the Thai constitution. The 1997 Constitution, known as the People's Constitution, recognizes the right to health in Article 52. The constitutional right to health was outlined and implemented in the eighth National Economic and Social

Development Plan and the National Plan for AIDS Prevention and Alleviation. The link between the national AIDS plan and the national development plan reflected the view of the Thai government that the HIV/AIDS epidemic was not only a medical crisis, but also a threat to the sustainable, social and economic development of the country.

At the request of Thai NGOs and NGOs from other countries negotiating FTAs with Thailand, the UN Special Rapporteur on the Right to Health sent a communication to the Thai government in October 2005 raising concern that other bilateral FTAs had omitted important public health safeguards and that this could threaten the enjoyment of the right to health. He recommended that all future trade agreements should safeguard respect for the right to health and access to essential medicines in particular.³⁷

In addition, the UN Committee on the Rights of the Child, which monitors the implementation of the Convention on the Rights of the Child, recommended in January 2006 that the Thai government should 'ensure that regional and other free trade agreements do not have a negative impact on the enjoyment of the right to health of children. More specifically, the Committee recommended that the Thai government ensure that such agreements will not negatively impact the availability of drugs and medicines for children.'³⁸

Therefore, in negotiating an FTA with the United States, Thailand should ensure that it can maintain and enact laws and policies that uphold the right to public health and promote broad access to safe, effective, and affordable medicines. Thailand's current patent legislation incorporates safeguard mechanisms to that end. Including provisions such as those contained in the US proposal which would require more strict intellectual property protection in Thai legislation would be the wrong policy choice for the many thousands of Thais living with HIV/AIDS, as well as for those suffering from other infectious and chronic diseases.

7 Conclusion

Oxfam shares the concerns of Thai NGOs that a Free Trade Agreement with the United States containing new stringent intellectual property rules could seriously undermine future access to affordable medicines in Thailand. Oxfam urges the United States to stop pressuring Thailand to implement 'TRIPS-plus' measures in the FTA, and instead to give maximum support to Thailand to use the flexibilities contained in TRIPS, such as compulsory licensing, in order to expand and ensure the sustainability of the Thai AIDS program that has successfully used generic medicines.

The case of HIV/AIDS in Thailand illustrates how stringent intellectual property protection could block access to affordable, life-saving medicines. But the problem is not limited to this disease. Thai people need other medicines to treat heart disease, diabetes, and cancer, for example. The rising incidence of resistant infections and chronic disease also require new, effective, and affordable medicines. Many of these medicines are, and will be, under patent and therefore too expensive for those who need them.

Oxfam therefore supports the call from Thai civil society organizations for the Thai government to make maximum use of compulsory licensing and other public health safeguards in order to allow poor people to gain access to affordable generic medicines, and to reject new 'TRIPS-plus' measures in the US-Thailand FTA.

Thailand already complies with the WTO TRIPS Agreement so there is no need for additional intellectual property provisions in an FTA – except to provide short-term commercial benefit to big pharmaceutical companies - to the detriment of Thai people. No FTA should trade away public health.

8 Recommendations

Thailand and the United States should halt FTA negotiations in order to carry out and take into account independent studies on the potential impact of proposed FTA provisions on public health.

Greater transparency is necessary throughout all FTA negotiations by disclosing the negotiating text to the public and making it available to all stakeholders. Furthermore, the concerns and proposals of civil society stakeholders should be taken into account in all negotiations. It is already clear from the leaked US negotiating proposal that the FTA could have serious implications for public health in Thailand, particularly in the treatment of HIV/AIDS. Before considering the adoption of such new policies, a much broader public debate is needed.

Any trade agreement negotiated between the United States and Thailand should not include any 'TRIPS-plus' measures, but rather should expressly include in the text affirmative support for Thailand's right to use the flexibilities provided under the WTO TRIPS Agreement, the Doha Declaration and its subsequent 30th August Decision, known as the 'TRIPS/health solution'. Furthermore, Thailand should consider exercising its right to the full use of compulsory licensing and should retain the discretion to determine the grounds upon which it can be used. No trade agreement should in any way serve to limit generic competition.

Obligations contained in other chapters of a potential trade agreement, particularly the investment and dispute settlement chapters, must not undermine the right of governments to use public health safeguards available to them under global trade rules.

Notes

¹ See Oxfam Briefing Notes: 'The US-Thailand FTA: Threatening the Livelihoods of Small-scale farmers in Thailand'; 'Make Trade Fair for the Americas'; 'Make Trade Fair for Central America'; 'A Raw Deal for Rice under DR-CAFTA.' All papers are available at www.oxfam.org/en/policy/.

² The Nation, Bangkok, January 3, 2006.

³ Thailand Ministry of Public Health, January 26, 2006. www.moph.go.th/ict/modern/. The World Bank and Thailand Ministry of Public Health (2005). 'Expanding Access to Antiretroviral Treatment in Thailand'.

⁴ B.G.Weniger *et al* (1991) 'The epidemiology of HIV infection and AIDS in Thailand', *AIDS Supp* 2:S71-S85.

⁵ World Bank and Thailand Ministry of Public Health (2005) 'Expanding Access to Antiretroviral Treatment in Thailand' p. 6.

⁶ Agence France Presse, 'Thailand: rate of HIV infection grows among Thai Teenagers', 3 January 2003.

⁷ Thai Working Group on HIV/AIDS Projections, Bangkok, 2001.

⁸ UNICEF (2004) 'East Asia: Children and HIV/AIDS', UNICEF, Bangkok, p.9.

⁹ UNDP (2004) 'Thailand's Response to HIV/AIDS: Progress and Challenges', UNDP, Bangkok, p.21.

¹⁰ World Bank 2005, *op.cit.*

¹¹ UNAIDS/WHO AIDS (2005) 'Epidemic update: December 2005'. www.unaids.org/epi/2005/doc/EPIupdate2005_html_en/epi05_06_en.htm

¹² International AIDS Society, www3.aegis.org/conferences/iac/2002/TuOrG1246.html

¹³ Under the universal healthcare system, the poor and uninsured persons are charged 30 baht per treatment at the government's health service units.

¹⁴ The Budget Act, The Bureau of the Budget, Office of Prime Minister and National Economic and Social Development Board (NESDB). Personal interview with an official at the Ministry of Public Health, December 2005.

¹⁵ UNAIDS and WHO (2004) '3 by 5' Progress Report, December, p.23. *The Nation*, Bangkok, January 3, 2006.

¹⁶ Investigation by Dr. Jakkrit Kuanpoth, Centre for Law and Sustainable Development in Asia and the Pacific.

¹⁷ P. Pothisiriet *et al.* (1998) 'Funding Priorities for HIV/AIDS Crisis in Thailand', paper presented at the 12th World AIDS Conference, Geneva, Switzerland, June, 1998.

¹⁸ Families USA (2005), 'The Choice: Health Care for People or Drug Industry Profits', September 2005 www.familiesusa.org/resources/publications/reports/the-choice.html

¹⁹ National Institute for Health Care Management (2002) 'Changing Patterns of Pharmaceutical Innovation', May 2002, p.3
www.nihcm.org/finalweb/innovations.pdf

²⁰ R&D expenditures by the US Department of Health and Human Services and the National Science Foundation totaled \$31 billion in 2003. PhRMA reported R&D expenditures of \$38 billion in 2004.

²¹ According to 2003 data from IMS Health. www.imshealth.com

²² Amy Harmon and Robert Pear, (2001) 'A nation challenged: the treatment; Canada overrides patent for Cipro to treat anthrax', *New York Times*, October 19, 2001.

²³ Press releases from US Senator Charles Schumer: October 16, 18, 19 and 20, 2005; December 8, 2005; and January 25, 2006.
<http://schumer.senate.gov/SchumerWebsite.pressroom/pr>

²⁴ World Bank 2005, *op.cit.* p.21.

²⁵ For further detail and legal analysis see Kuanpoth, J. (2006) 'Patents and Access to Medicines in Thailand – The ddl case and beyond', *Intellectual Property Quarterly*, Issue 2, 2006.

²⁶ World Bank 2005, *op.cit.* p.14.

²⁷ The US proposal on patents and related protections for pharmaceuticals was apparently leaked following the US-Thai negotiating session in January, 2006, where it was first presented, and was posted on the internet. See: www.bilaterals.org/article.php3?id_article=3677

²⁸ United States Trade Promotion Authority, Public Law 107-210, August 6, 2002, § 2102(b)(4)(C).

²⁹ Civil society and parliamentarians have repeatedly attempted to clarify this concern with USTR. To date, USTR has not included in the text of any US-FTA a legally binding clarification that would ensure that data protection would be overridden when a compulsory license is issued. Appropriate language was proposed by Andean countries and rejected by USTR in the US-Andean FTA negotiations. Side letters included in some recent FTAs do not constitute a legally binding exception from the very clear obligations in these agreements.

³⁰ For example, AZT, the first drug on the market to treat HIV/AIDS, was first patented in 1964 as a potential drug to treat cancer, although it was found not to be effective. However, 20 years later it was granted a new patent after it was found to be effective against AIDS.

³¹ A similar law in India recently allowed for an invalid patent claim on the leukemia drug Gleevac to be successfully challenged before rather than after the patent was granted.

³² Charter of the United Nations, Arts. 1, 55 and 56.

³³ Universal Declaration on Human Rights, Art.25.

³⁴ Convention on the Rights of the Child, Art.24.

³⁵ UN Committee on Economic, Social and Cultural Rights (2000) 'The right to the highest attainable standard of health' General Comment 14, (Art. 12), 4 July, UN Doc. E/C.12/2000/4, paras. 9 and 12.

³⁶ UN Commission on Human Rights, Resolution 2001/3 (12 April 2001), UN Doc. E/CN.4/2001/L.50.

³⁷ UN Commission on Human Rights, Report of the Special Rapporteur on the right of everyone to the highest attainable standard of physical and mental health, Paul Hunt, Summary of communications sent to and replies received from Governments and other actors, UN Doc. E/CN.4/2006/48/Add.1, paragraphs 24 and 25, December 2005.

³⁸ UN Committee on the Rights of the Child, Thailand, Concluding Observations, UN Doc. CRC/C/THA/CO/2, January 2006.

© Oxfam International April 2006

This paper was written by Gawain Kripke and Stephanie Weinberg, based on research by Dr Jakkrit Kuanpoth. Oxfam acknowledges the assistance of Mohga K. Smith, Ruth Mayne, Matthew Coghlan, Yowalak Thiarachow, Chalernsak Kittitrakul, Pariphan Uawithya, Katherine Daniels, Jennifer Brant, Dr Marc Lallemand (PHPT), Dr. Gonzague Jourdain (PHPT), Intira Collins (PHPT), Sanya Reid Smith (TWN) and the AIDS Access Foundation. It is part of a series of papers written to inform public debate on development and humanitarian policy issues.

The text may be used free of charge for the purposes of advocacy, campaigning, education, and research, provided that the source is acknowledged in full. The copyright holder requests that all such use be registered with them for impact assessment purposes. For copying in any other circumstances, or for re-use in other publications, or for translation or adaptation, permission must be secured and a fee may be charged. E-mail publish@oxfam.org.uk.

For further information on the issues raised in this paper or the Make Trade Fair campaign, please e-mail advocacy@oxfaminternational.org or visit www.maketradefair.com.

Oxfam International is a confederation of twelve organizations working together in more than 100 countries to find lasting solutions to poverty and injustice: Oxfam America, Oxfam Australia, Oxfam-in-Belgium, Oxfam Canada, Oxfam Germany, Oxfam Great Britain, Oxfam Hong Kong, Intermón Oxfam (Spain), Oxfam Ireland, Oxfam New Zealand, Novib Oxfam Netherlands, and Oxfam Quebec. Please call or write to any of the agencies for further information, or visit www.oxfam.org.

Oxfam International Advocacy Offices:

Washington: 1100 15th St. NW, Ste. 600, Washington, DC 20005, USA

Tel: +1.202.496.1170. E-mail: advocacy@oxfaminternational.org

Brussels: 22 rue de Commerce, 1000 Brussels, Belgium

Tel: +322.502.0391. E-mail: luis.morago@oxfaminternational.org

Geneva: 15 rue des Savoises, 1205 Geneva, Switzerland

Tel: +41.22.321.2371. E-mail: celine.charveriat@oxfaminternational.org

New York: 355 Lexington Avenue, 3rd Floor, New York, NY 10017, USA

Tel: +1.212.687.2091. E-mail: nicola.reindorp@oxfaminternational.org

Tokyo: Oxfam Japan, Maruko-Bldg. 2F, 1-20-6, Higashi-Ueno, Taito-ku, Tokyo 110-0015, Japan

Tel/Fax: +81.3.3834.1556. E-mail: advocacy@oxfaminternational.org

<p>Oxfam America 26 West St. Boston, MA 02111-1206 USA Tel: +1.617.482.1211 E-mail: info@oxfamamerica.org www.oxfamamerica.org</p>	<p>Oxfam Hong Kong 17/fl., China United Centre 28 Marble Road, North Point Hong Kong Tel: +852.2520.2525 E-mail: info@oxfam.org.hk www.oxfam.org.hk</p>
<p>Oxfam Australia 156 George St. Fitzroy, Victoria 3065 Australia Tel: +61.3.9289.9444 E-mail: enquire@caa.org.au www.oxfam.org.au</p>	<p>Intermón Oxfam (Spain) Roger de Llúria 15 08010, Barcelona Spain Tel: +34.902.330.331 E-mail: info@intermonoxfam.org www.intermonoxfam.org</p>
<p>Oxfam-in-Belgium Rue des Quatre Vents 60 1080 Brussels Belgium Tel: +32.2.501.6700 E-mail: oxfamsol@oxfamsol.be www.oxfam.be</p>	<p>Oxfam Ireland <u>Dublin Office</u>, 9 Burgh Quay, Dublin 2 Ireland, Tel: +353.1.672.7662 <u>Belfast Office</u>, 115 North St, Belfast BT1 1ND, UK, Tel: +44.28.9023.0220 E-mail: communications@oxfam.ie www.oxfamireland.org</p>
<p>Oxfam Canada 250 City Centre Ave, Suite 400 Ottawa, Ontario, K1R 6K7 Canada Tel: +1.613.237.5236 E-mail: info@oxfam.ca www.oxfam.ca</p>	<p>Oxfam New Zealand PO Box 68357 Auckland 1032 New Zealand Tel: +64.9.355.6500 (Toll-free 0800 400 666) E-mail: oxfam@oxfam.org.nz www.oxfam.org.nz</p>
<p>Oxfam Germany Greifswalder Str. 33a 10405 Berlin Germany Tel: +49.30.428.50621 E-mail: info@oxfam.de www.oxfam.de</p>	<p>Novib Oxfam Netherlands Mauritskade 9, Postbus 30919 2500 GX, The Hague The Netherlands Tel: +31.70.342.1621 E-mail: info@novib.nl www.novib.nl</p>
<p>Oxfam Great Britain Oxfam House, John Smith Drive Cowley, Oxford, OX4 2JY, UK Tel: +44.(0)1865.473727 E-mail: enquiries@oxfam.org.uk www.oxfam.org.uk</p>	<p>Oxfam Québec 2330 rue Notre Dame Ouest, bureau 200 Montréal, Quebec, H3J 2Y2, Canada Tel: +1.514.937.1614 E-mail: info@oxfam.qc.ca www.oxfam.qc.ca</p>