

HIV/AIDS medicines for all?

The consequences of ignoring the real threat to access to essential HIV/AIDS medicines

Tim Wilson



From the Executive Director

There are few more important issues facing developing nations than the HIV/AIDS crisis. HIV/AIDS destroys lives, consumes scarce resources, and provides yet another unneeded brake on the path to growth for many developing nations.

The developed world already has readily available medicines which can help alleviate the effects of HIV/AIDS. The challenge is to make these medicines available to as many people as possible. According to some non-government organisations, the reason why people are denied access to life-saving drugs is because of patent protections. In fact, nothing could be further from the truth.

As 'HIV/AIDS Medicines For All?' reveals, patent protections are not the reason why people in developing countries do not have the same access to medicines as those in developed countries. Instead, much of the blame can be placed upon the all too familiar barriers of government regulation, taxes and tariffs that are mistakenly viewed by developing nations and their self-appointed advocates as the means to achieve prosperity.

The Institute of Public Affairs (IPA) has long been an advocate for private property rights in all sectors of the economy, and the IPA has been an active player in the debate on intellectual property. Earlier this year the Institute made a submission to the Department of Foreign Affairs & Trade inquiry into the inclusion of the TRIPS Public Health Amendment. The IPA has published numerous articles in its journal, the *IPA Review*, on intellectual property, the 'fair trade' movement and public health policy. The IPA has also been active in the debate on intellectual property and parallel imports.

Intellectual property rights, like rights that accrue to physical property, provide a stable legal framework for innovation and development. Unfortunately the campaign against patent protection is a threat not just to innovation, but to the health of millions of people in the developing world.



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Executive Summary

The International AIDS Society Conference on HIV Pathogenesis, Treatment and Prevention to be held in Sydney, Australia in late July convenes at a critical time in the global fight against HIV/AIDS. Over the last decade, as the AIDS crisis has continued to evolve around the world, the global health community has increased its efforts to determine how best to broaden access to life-saving medicines. At the same time, the community understands the need to ensure that incentives remain for scientific research and development into the next generation of medical technologies.

Several international non-government organisations (NGOs) have blamed patent protections on HIV/AIDS medicines for pricing developing world patients out of the market. Patents, they claim, are a barrier to access. This claim has been amplified by the media. And these NGOs have lobbied governments to break patents.

In response to these claims, the scholarly community has investigated the role that patents play in blocking access. Several papers and reports have painted a much more complex picture than that typically reported in press accounts or found in NGO press releases.

As this paper demonstrates, patents do not serve as a significant barrier to treatment. Moreover, there are several barriers to access over which policymakers and aid groups have some influence and yet which receive little attention in the media. The patient community would be well-served by increased attention paid to these barriers.

For example, our research finds that government regulation, duties, taxes and tariffs can represent more than half of the final cost of medicines in the developing world. These tariffs are illegal in developed economies, but continue to be imposed in developing countries at the expense of the world's poor.

Research also demonstrates that generic medicines are often as expensive or more expensive than patented drugs. For example, one recent scholarly survey found that of 18 single dose AIDS medicines available in developing countries, 14 patent-protected drugs were either cheaper or in a similar price range to their generic counterparts.

Of particular interest to the media and the global policy community is the Trade-Related Aspects of Intellectual Property Rights Agreement (TRIPS) in the World Trade Organisation. The TRIPS Agreement allows developing countries to break patents and issue compulsory licenses for medicines but only in times of 'national emergency'.

Thailand and Brazil have recently issued compulsory licenses for HIV/AIDS medicines. Thailand has also issued a compulsory license for a heart disease medicine. In both cases, the government claimed financial hardship prevented it from paying for innovator medicines and thus justified the breaking of patents.

Yet our analysis shows that the actions taken by the military government of Thailand are largely without merit. To give one small illustration: at the same time it claimed financial hardship and slashed its public health budget, the Thai military government also increased military spending by more than US\$1.1 billion.

The actions by the Thai government are in line with a larger international effort to undermine intellectual property (IP) protections. But one frequently overlooked aspect of this effort is that the failure to enforce patent protections is also contributing to the spread of counterfeit medicines. These counterfeits pose a serious risk to global health by promoting resistance to HIV/AIDS medication, with worrying medical and financial consequences.

Undermining property rights through the issue of compulsory licenses will have a detrimental impact on investment that is vital to address the healthcare infrastructure and supply chain challenges developing countries face.

Introduction

This paper has been developed by the Institute of Public Affairs in the lead up to the International Aids Society Conference on HIV Pathogenesis, Treatment and Prevention to be held in Sydney, Australia, July 22-25 2007. The core purpose of the paper is to educate interested parties on the issues and implications of policy decisions currently being made in relation to the development and distribution of HIV/AIDS medicines.

Since its inclusion at the end of the Uruguay Round of World Trade Organisation negotiations, the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement has required developing countries to introduce and enforce intellectual property rights regimes. Non-government organisations have regularly condemned TRIPS for its requirement to encourage drug innovation and development through patent protections. NGOs have claimed that patents keep the price of essential medicines high and thus inaccessible for the world's poor.

The TRIPS Agreement contains an allowance for countries to issue compulsory licenses and temporarily suspend patents in cases of 'national emergency'. Following the recent action of the Thai government to issue compulsory licenses for three medicines, two HIV/AIDS and one heart medicine, there has been significant international debate about the legitimacy and applicability of compulsory licensing and the role patents play in the price of medicines.

This paper investigates the role patents play in setting the prices of medicines in the developing world. It also considers other factors that affect prices and the implications of compulsory licenses on research and innovation, medicine prices and the subsequent impact on patient's health.

The IPA has taken an interest in this policy area as part of its approach to develop evidence-based public policy solutions that deliver outcomes. Too often public policy is developed and solutions are proposed that are not supported by evidence. This paper highlights similar concerns in developing public policy solutions for access to HIV/AIDS medicines for the world's poor.

The campaign against patents

In recent years NGOs such as Médecins Sans Frontières (MSF), known in Australia as Doctors without Borders, Oxfam International, and Knowledge Ecology International (KEI) have run international campaigns highlighting the limited access to essential medicines by the world's poor.

A core target of their campaigns has been IP rights and the WTO's TRIPS Agreement that requires WTO members to have and enforce IP rights regimes. Their criticism of TRIPS and the obligations it imposes relates to enforceable patents on innovative medicines which they claim keep the price of medicines in the developing world high and hence undermine access.

Patents grant the innovator the right to exploit the patented medicine for a period of up to 20 years; though due to regulatory approval processes, the period is normally halved. By granting the innovator an exclusive right to manufacture a medicine NGOs have argued that the price of a medicine is kept artificially high and removes competition that would otherwise reduce the price of medicines in the interests of pharmaceutical companies at the expense of the world's poor.

Since 1999, the French NGO MSF has run its 'Campaign for Access to Essential Medicines', focusing on increasing access for essential medicines in the developing world. MSF has been particularly vocal in supporting a recent decision by the Thai government to issue compulsory licenses for three medicines, stating that 'the lives of patients have to come before the patents of drug companies, and this policy needs to be expanded to essential drugs that are expensive and in short supply'.¹

In the lead up to the 2006 Toronto World Aids Conference Oxfam International added pharmaceuticals into its 'Make Trade Fair' campaign. It has since joined MSF's chorus arguing patents 'push up the price of essential products like ... medicines ... (ensuring) vital drugs will be priced out of reach of poor people ... (and) many of these lives could be saved if cheap drugs were available'.²

KEI have also been active. Following the announcement by Brazil to issue a compulsory license for AIDS drug efavirenz, KEI's Director, James Love, commented that it 'is an important first step ... (and) we wish Brazil had done this in 2001, when it was first proposed'.³

TRIPS and compulsory licensing

There are many myths surrounding the role of TRIPS, patents and compulsory licensing, that distort debate and consideration of sound public policy solutions to the challenge of access to essential medicines for the world's poor.

During the Uruguay Round of General Agreement on Tariffs and Trade negotiations, the contracting parties negotiated the inclusion of the TRIPS Agreement under the newly formed WTO. The TRIPS Agreement requires WTO members to introduce and enforce IP rights regimes.

Due to concerns about the potential impact of IP rights regimes on access to essential medicines, the TRIPS Agreement includes provision for compulsory licensing under Section 31 (b). Compulsory licensing allows countries to waive patents following consultation with the patent holder in a 'national emergency or other circumstances of extreme urgency or in cases of public non-commercial use'.⁴ Section 31 (f) of TRIPS states that compulsory licenses should only be issued to provide products for domestic purposes.

Despite the flexibility afforded in TRIPS to deal with health crises, developing countries sought further clarification. Following the 2001 Doha Ministerial of the WTO the Doha Declaration provided clarity to ambiguities in the text of the TRIPS Agreement on the issuance of compulsory licenses. The Doha Declaration made it clear that each country was allowed to individually interpret a 'national emergency or other circumstance of extreme urgency' and that this included HIV/AIDS.⁵

Following further negotiations concluded in 2003, the WTO also allowed members who did not have the manufacturing capacity to produce compulsory licensed medicines to trade in generic medicines. Technically all WTO members were entitled to do so, but developed country members waived their rights. This amendment was implemented as an immediate interim measure and is currently under consideration for formal inclusion into the TRIPS Agreement. Considering that the United States has already announced its support for the inclusion, it is expected to be included shortly.

The inclusion of compulsory licensing in TRIPS, and the clarity provided to their issuance, was negotiated with the expectation that WTO members would exercise this right sparingly. Recent actions by the governments of Thailand and Brazil demonstrate otherwise.

Compulsory licensing by Thailand's Military junta

In early 2007 the new military government of Thailand issued compulsory licenses for patented medicines under the 'national emergency' provisions of the TRIPS Agreement. The Thai government originally threatened to issue compulsory licenses for 14 medicines and subsequently issued them for three—two HIV/AIDS antiretrovirals, Kaletra and efavirenz, and a widely-used heart

disease medicine, Plavix.⁶

The Thai government identified budgetary constraints as the primary reason for issuing compulsory licenses for these medicines. In its issuance of a compulsory license for Kaletra the Thai government stated that 'with this high price the budget allocated from the Thai government can only cover some patients ... if this ARV formula could be produced or imported, the lower price would help more accessibil(ity)'.⁷

The Thai Health Minister stressed the implications of cost stating 'the move is permissible under international trade rules in the event of national public health emergencies ... we have to do this because we don't have enough money to buy safe and necessary drugs for the people under the government's universal health scheme'.⁸

Under its TRIPS obligations the Thai government was required to consult with the patent holder. The pharmaceutical companies affected included Abbott Laboratories (Kaletra), Sanofi-Aventis and Bristol-Myers Squibb (Plavix). Yet the Thai government did not consult with these companies, and all made efforts to consult with the Thai government following the announcement, with limited success.⁹

Following the threat of the compulsory license for Kaletra, Abbott Laboratories offered to reduce the price of Kaletra to below the cost of any copy version currently available. The Thai government turned down Abbott's offer and proceeded with the compulsory license.

Oxfam and MSF have been particularly vocal running campaigns in favour of the actions of the Thai military government and against retaliatory action of affected pharmaceutical companies.¹⁰

The cosy relationship between Oxfam and MSF with the Thai military junta is a marker for the credibility of these organisations. MSF brands itself as an 'international medical humanitarian organisation' and Oxfam claims to be 'united for a more equitable world'. Yet they are now building close relationships and garnering support for a unelected, undemocratic military junta with scant regard for human rights.¹¹

Thailand's action is setting a dangerous precedent. Following the actions of Thailand, the government of Brazil has also now issued compulsory licenses for efavirenz, despite offers by Merck to reduce its price for the medicine.¹²

Spurious claims at best

In issuing compulsory licenses for Kaletra, efavirenz and Plavix the Thai government cited a 'national emergency' due to a lack of funds to purchase the patented medicines. The Thai government has waived the patents and allowed the medicines to be produced by the government owned

Government Pharmaceutical Organisation (GPO). Despite its obligations under TRIPS to not issue compulsory licenses for profit, the GPO is a profit making company with a deplorable record of commitment to the public health of the Thai people.

In 2005 the GPO made a profit of US\$35.5 million and reinvested only 0.5% of its sales revenue into research and development (R&D). This compares poorly with innovative pharmaceutical companies that reinvest approximately 17.5% of their sales revenue in R&D.¹³

Making profits from pharmaceuticals is a fair and reasonable enterprise. But there is an inconsistency when a government agency is making annual profits of US\$35.5 million, while the government concurrently argues it cannot afford medicines and must invoke compulsory licensing; particularly when the estimated cost saving to the Thai government from these compulsory licenses is only US\$30 million per annum.¹⁴

Concurrently the Global Fund to Fight AIDS, Tuberculosis and Malaria, commonly known as the Global Fund, an organisation funded by primarily developed country governments to fight against the aforementioned diseases, offered to pay for the Thai government's needs for efavirenz from a World Health Organisation (WHO)-approved generics producer in India. Yet the Thai government turned down the offer, preferring the Thai taxpayers foot the bill.

The Thai government has had a questionable commitment to prioritising health spending. In 2003, government health expenditure was 3.3 percent of GNP, down from 3.5 percent in 1999, while total government expenditure grew from 54 percent in 1999 to 62 percent in 2003. This compares poorly with other developing countries such as China with 5.6 percent, Cambodia with 10.9 percent and Vietnam with 5.4 percent.¹⁵

The Thai military government has also cut health spending by US\$12 million per annum. If the government were in a tight financial spot this would be understandable, but at the same time they also increased salaries to military officials by US\$9 million and defence spending by a third, or US\$1.1 billion.¹⁶

But these are not the limits to the questionable conduct of the Thai government. In 2002 the Thai Auditor General reported that the GPO had stolen around US\$13 million from the Thai government over the previous 4 years, by selling more than 60 percent of its medical products to the government above market price, in some cases by as much as 1,000 percent.¹⁷

The GPO also has a terrible track record of protecting the health interests of the Thai people. In 2002 the Global Fund provided US\$133 million to the GPO to test its locally produced HIV/AIDS medicine, GPO-Vir. In July of that year it was discovered that the GPO was issuing substandard medicines that were ineffective and promoted

resistance to first-line treatment for HIV/AIDS patients.

By August of that year the Global Fund withdrew its financial support because the GPO had not achieved WHO approval and was not meeting international standards. Yet, despite the relatively weak standards imposed by the WHO, the GPO has failed to meet their standards against every benchmark.¹⁸

A WHO spokesperson made specific comment on the WHO's action stating that 'drugs that are not WHO pre-qualified may not directly kill people, but they could foster resistance to aids drugs'.¹⁹ This appears to be precisely what has occurred in Thailand. The WHO also recommended that the medicine not be sold outside of Thailand because it failed to achieve bioequivalence.

A bioequivalent medicine is one that is a true generic medicine and has been approved by the relevant regulatory agency such as the Therapeutic Goods Administration in Australia or the Food and Drug Administration in the United States.

A generic medicine is different from a copy or counterfeit medicine. A counterfeit medicine has not gone through government quality and regulatory processes. Without quality assurance processes, a copy or counterfeit medicine has the potential to include insufficient active ingredients which can promote resistance to effective medicines. In some cases counterfeit medicines include dangerous substitutes for active ingredients that can be both ineffective and deadly.

The consequence of providing substandard medicines that do not achieve bioequivalence is that patients then develop resistance to the medicine, rendering it ineffective against their disease. In the case of Antiretroviral medicines (ARVs) the use of substandard medicines promotes resistance from first-line therapies and requires patients to use second-line or third-line therapies.

First-line therapies are the cheapest and most common form of ARVs. The cost of moving patients onto second-line therapies is significant and requires a higher level of care with supportive infrastructure and medical services, including specialist physicians, ongoing monitoring and potential hospitalisation. By supplying medicines that promote resistance to shave costs, the Thai GPO is both placing the lives of patients at risk and creating a long-term financial problem to provide medicines to people infected with HIV/AIDS.

Estimates include nearly a ten-fold increase in the cost if patients are required to move to second-line treatments. Drug resistance is also cumulative. It is estimated that up to 45 percent of Thailand's AIDS patients are now drug resistant.²⁰

It is clear that if the Thai government continues to use medicines that promote resistance, the real national health emergency has yet to hit Thailand, and it will not be able to allocate blame to patented medicines.

Patents are not the problem

In relation to the Thai government, NGOs claim that IP rights are making medicines cost prohibitive for the world's poor. This position is not supported by evidence.

The WHO maintains an Essential Medicines List (EML) that provides guidance on 'a list of minimum medicine needs for a basic health care system, listing the most efficacious, safe and cost-effective medicines for priority conditions'.²¹ If IP rights were the source of the price problem for developing countries the WHO EML would be filled with patented medicines that are provided at unreasonably high prices for the population. Yet a study conducted showed that of the medicines listed on the WHO's EML, 98 percent were not patented in poor countries.²²

Undermining IP rights didn't increase Indian access

The lack of enforced IP rights regimes also has a detrimental impact on foreign and local pharmaceutical companies developing medicines targeting local health challenges.

India provides a telling example of the costs of not having IP rights. In 1972 the government of India passed laws that ceased patents on pharmaceuticals to drive down prices. Despite the rhetoric, access to medicines did not increase because of the removal of patents.

India has the highest number of AIDS patients of any country in the world. Much of the burden for financing medicines for India's AIDS patients falls onto the international donor community, not the domestic government. Yet even without patents, only 12,000 of India's estimated five million AIDS sufferers were receiving AIDS medicines by the end of 2005.²³

Instead of increasing access to essential medicines, abolishing patents for pharmaceuticals limited the growth of an Indian innovative medicines industry.²⁴ India did become the centre of generic medicines with more than 15,000 generic pharmaceutical firms in 2002,²⁵ but the benefit has not flowed on to Indians infected with HIV/AIDS.

Recently, India changed its regime to support IP rights for pharmaceuticals. Since the introduction of IP rights local firms, such as Ranbaxy and Dr Reddy's, have begun R&D in medicines that primarily target the local population. In the last five years, India has doubled the number of medicines approved by the FDA and is now the country with the single largest number of medicines approved by the FDA after the United States.²⁶

Generics needn't be cheap

A myth has been created that patents provide a monopoly for the inventor that drives up prices, while generics are a cheaper alternative to secure access to essential medicines for the world's poor. Patents certainly allow the patent holder exclusive rights, but a patent holder's monopoly is tenuous.

A medicine that achieves the same outcome can be developed by different means without being in breach of a patent. Only the precise formula for the patented medicine and the process for its application can be patented.

Patents also don't provide the exclusive period of exploitation that is commonly perceived. Under TRIPS countries are required to provide patents for at least 20 years. A patent's priority date indicates the date it was filed. A pharmaceutical's priority date is filed prior to application for regulatory approval to manufacture the medicine. By the time regulatory approval is achieved the period for monopoly manufacture is reduced by half or more.

In the absence of patents NGOs suggest that generics will provide a cheaper alternative to patented medicines. MSF's own numbers do not support this claim. In 2005 the Hudson Institute completed a study of MSF's 'Untangling the web of price reductions' report identifying the price differences between patented and non-patented medicines. Out of the 18 single dose AIDS medicines listed in MSF's report, five were cheaper than the generic variety, only four were more expensive and the remaining nine were in a comparable price range.²⁷

The study also found that none of the fixed dose combination medicines were higher than the generic, and one was nearly a quarter of the price.

The basis for arguing that developing countries will have greater access to essential HIV/AIDS drugs through compulsory licensing of generic HIV/AIDS medicines is questionable.

Government policies increase prices

Despite the rhetoric of NGOs, IP rights are not barriers for access to patented medicines. One of the most important and most easily removable barriers for access to essential medicines for the world's poor is the removal of developing country government regulation, taxes and tariffs.

During the Uruguay Round of WTO negotiations developed countries agreed to remove all tariffs on pharmaceutical imports. As developing countries were not signatories to this agreement, they are allowed to continue applying regressive tariffs on essential medicine imports.

The WHO has made it clear that improving access to affordable medicines requires 'reducing taxes, tariffs

Table 1: Prices of Single Dose AIDS Medicines

Single Dose ARV	Patented Drug Price (Transportation included)	Copy Price Range (10% Transportation included)	Comparability
Abacavir, 300mg	\$887	\$776 - \$1,445	Same range
Didanosine, 100mg	\$310	\$161 - \$456	Same range
Didanosine, 400mg	\$279	\$179 - \$368	Same range
efavirenz, 200mg	\$500	\$361 - \$482	More expensive
efavirenz, 600mg	\$347	\$381 - \$519	Less expensive
Indinavir, 400mg	\$400	\$353 - \$514	Same range
Lamivudine, 150mg	\$69	\$60 - \$188	Same range
Lamivudine, 10mg	\$82	\$64 - \$84	Same range
Nelfinar, 250mg	\$1,036	\$1,245 - \$1,967	Less expensive
Nevirapine, 200mg	\$438	\$88 - \$183	More expensive
Nevirapine, 10mg	\$401	\$93 - \$153	More expensive
Ritonavir, 100mg	\$91	\$225 - \$482	Less expensive
Saquinavir, 200mg	\$1,059	\$1,124	Less expensive
Stavudine, 30mg	\$48	\$15 - \$66	Same range
Stavudine, 40mg	\$55	\$35 - \$84	Same range
Stavudine, 1mg/ml	\$35	\$88	Less expensive
Zidovudine, 300mg	\$212	\$154 - \$319	Same range
Zidovudine, 10mg	\$223	\$105 - \$130	More expensive

Source: Adapted from Adelman, C., Norris, J. & Weicher, S. J., 'Access to Medicines: The Full Cost of HIV/AIDS Treatment', White Paper, Hudson Institute, e2, May 2005, p9, modified from Médecins Sans Frontières, 'Untangling the Web of Price Reductions: A Price Guide for the Purchase of ARVs for Developing Countries', February 2005, pp10-12

Table 2: Prices of Fixed Dose Combination Medicines

Fixed dose combination ARV	Patented Drug Price (Transportation included)	Copy Price Range (10% Transportation included)	Comparability
Lamivudine (300mg) + Zidovudine (150mg) + Abacavir (300mg)	\$1,241	\$1,132 - \$1,737	Same range
Lamivudine (150mg) + Zidovudine (300mg)	\$237	\$201 - \$469	Same range
Lopinavir (133.3mg) + Ritonavir (33.3mg)	\$550	\$2,168	Less expensive

Source: Adapted from Adelman, C., Norris, J. & Weicher, S. J., 'Access to Medicines: The Full Cost of HIV/AIDS Treatment', White Paper, Hudson Institute, e2, May 2005, p9, modified from Médecins Sans Frontières, 'Untangling the Web of Price Reductions: A Price Guide for the Purchase of ARVs for Developing Countries', February 2005, pp10-12

and margins'.²⁸ In its Price, Availability and Affordability report the WHO has consistently pointed out that taxes and tariffs are adding significantly to the cost of essential medicines. In its 2005 report the WHO noted that 'due to the cumulative nature of price components, a small tax applied early in the distribution chain (such as an import tax) can have a significantly larger impact on the final price'.²⁹ The WHO reiterated this point in its 2006 report stating 'One major finding was that taxes and duties levied on medicines, as well as mark-ups applied, frequently contribute more to the final price than the manufacturers' price'.³⁰

The global average for custom duty, value-added tax and other duties on pharmaceuticals averaged at 18 percent internationally and 14 percent in least developed countries.³¹

A 2003 Boston University Study found that of the nine developing countries surveyed that medicines were increased by up to 68.6 percent of their cost in country.³² Table 3 demonstrates why these costs can be crippling to

access to medicines. The table quantifies these costs in percentages, disguising their compounding implications that are reflected in the 'Total markup' row.

These countries provide indicative costs added to medicines before they reach their patient. Some are avoidable, others are not. Taxes and tariffs are particularly avoidable as they provide no purpose than to inflate the price of medicines to provide revenue to the government. Table 4 identifies some of the most egregious application of duties and taxes imposed by developing country governments that inflate the price of medicines.

Despite duties, taxes and tariffs making a significant contribution to the cost of essential medicines, they are rarely the focus of NGOs. If developing countries were focused first on their population's health and not fundraising, they would remove the taxes and tariffs applied to essential medicines.

Regulation also adds significant costs. South Africa has one of the highest rates of HIV/AIDS infection in the world; it also has a reputation for having one of the

Table 2: Examples of hidden costs on pharmaceuticals by country (%) of final cost

	Sri Lanka	Kenya	Tanzania	South Africa	Brazil	Armenia	Kosovo	Pune, India	Nepal	Mauritius
Import tariff	0	0	10		11.7	0	1	0	4	5
Port charges	4	8	1				4	0		
Clearance and freight		1	2						1.5	5
Pre-shipment inspection		2.75	1.2							
Pharmacy board fee			2							
Importer's margin	25						15	25	10	
VAT				14	18	20	0			
Central govt Tax								4		
State govt tax					6			9		
Local town duty								1.5		
Wholesaler	8.5	15	0	21.2	7	25	15	10	10	14
Retail	16.25	20	50	50	22	25	25	15	16	27
Total markup	63.97	54.22	74.3	74.05	82.38	87.5	73.64	81.94	48.08	59.26

Source: Levison, L., 'Policy and programming options for reducing the procurement costs of essential medicines in developing countries', Boston University School of Public Health, 2003

Table 4: Duties and taxes on retail medicines

Country	Combined total duties and taxes
India	55%
Sierra Leone	40%
Nigeria	34%
Pakistan	33%
Bolivia	32%
Bangladesh	29%
China	28%
Jamaica	27%
Morocco	25%
Georgia	25%
Mexico	24%

Source: Ahmed, K., Cudjoe, F., Davie, E., Kilama, D., Krause, M., Mejia, A., Mitra, B., Oplas, N., Simonetta, M., Stevens, P. (Ed), Tapia, J., Tse, M. & Urbach, J., 'Increasing access to medicines' in 'Fighting the Diseases of Poverty', International Policy Press, UK, 2007, p149

slowest approval mechanisms for regulatory approval for essential medicines.

South Africa's Medicines Control Council (MCC) has a reputation for unnecessary delays and inefficiency in the approval of medicines. The MCC can take more than three years to give regulatory approval for medicines already approved by developed country regulatory agencies.³³ These delays extend the period until patients can access essential medicines that have already proven to be safe.

Extended periods of regulatory approval also add to the cost of pharmaceutical companies, which is then passed on to consumers. In many developing countries the absence of a commercial market places a disincentive to seeking regulatory approval, effectively denying the access of people in those countries to the benefits of the medicine. Even if generic manufacturers supply medicines in their place, it reduces competition in the marketplace that would otherwise reduce the price of the medicines available.

Cheaper medicines needn't reach their destination

Taxes and tariffs are not the only significant inhibitor to access to essential medicines. Despite significant programs established by developed countries and donor

organisations to deliver access, many never receive treatment due to poor infrastructure and corruption.

Many ARVs are not even patented in parts of Africa and Asia, yet more than 50 percent of people lack regular access to essential medicines due to poor infrastructure for their supply and use.³⁴

The impact of poor infrastructure and poor health systems cannot be underestimated. In July 2006 the WHO's HIV Division stated that 'it is very obvious that the elephant in the room is not the current price of drugs. The real obstacle is the fragility of the health systems. You have health infrastructure that is dilapidated, and supply chains that do not exist'.³⁵

Poor healthcare infrastructure undermines the capacity for healthcare providers to deliver effective treatment. ARV treatment requires close monitoring and surveillance over the lifetime of the patient. Inadequate healthcare infrastructure makes this process exceptionally difficult.

Reliable supply chains are also essential. Less developed countries often lack the basic infrastructure to distribute medicines effectively due to poor or limited road networks and limited access to electricity. Poor road networks reduce the capacity for regular supply of essential medicines. A lack of reliable electricity undermines the security of supply for many complex HIV/AIDS medicines

that require refrigeration.³⁶

Corruption also plays an important role in undermining the successful delivery of medicines. As the example of the Thai GPO demonstrates, the GPO acts more in the interests of corrupt Thai bureaucrats and government officials, than in the interests of effectively delivering medicines to the Thai people. Studies have shown in Guinea, Cameroon, Uganda and Tanzania between 30 and 70 percent of government medicines disappeared before they reached their intended patients.³⁷

Ignoring these important issues does nothing to promote access to essential medicines. Yet NGOs like MSF, Oxfam and KEI frequently ignore these barriers and focus on IP rights and promote compulsory licensing. Sadly the cost of this position is routinely ignored, particularly when the impact will hit the world's poor hardest.

The consequences of ignoring the real barriers to access

Ignoring the real barriers to access will not aid the world's poor. But the alternative policy proposals by NGOs will also have a significant impact on their interests. Compulsory licensing has a substantial effect on foreign direct investment (FDI), forcing pharmaceutical companies to reassess their pricing policies and a failure to enforce IP rights promotes the production and use of life-threatening counterfeit medicines.

The cost to investment

Stable investment flows are essential to economic growth in the developing world. The benefits of FDI to economic growth can ensure availability of capital to fund the infrastructure and supply chains necessary to bridge the current gap between the supply of HIV/AIDS medicines and needy patients.

Undermining IP rights will have the long term effect of undermining investment. While issuing compulsory licenses for medicines in a 'national emergency' may be accepted by the international investment community, issuing compulsory licenses without consultation and for non emergency medicines, such as Plavix, is excessive.

The compulsory license action of the Thai government without consultation of the affected companies has significantly damaged its reputation as a centre for FDI. The US Chamber of Commerce completed a survey of business leaders that demonstrated that Thailand's economic policies and undermining of property rights is impacting on US investment decisions. Thailand has also recently earned its place on the United States Trade Representative's Priority Watch List because of its compulsory license action citing a 'lack of transparency and due process'.³⁸

In the Inaugural International Property Rights Index Thailand placed 40th out of the 70 countries indexed for intellectual property protection.³⁹

IP rights are essential to economic development. Physical property rights are an essential pillar for countries to grow economically. IP rights are no different. As the example of India demonstrates, IP rights are essential to driving investment to innovation and developing the IP-dependent industries in countries.

Where property rights are not enforced, goods and services fail to attract investment.⁴⁰ Stifled investment stymies innovation and the optimisation of limited resources. It ensures that individuals cannot prove their ownership and their access to credit is therefore limited.

The opportunities foregone are borne by individuals and society as a whole.⁴¹ This is particularly true of solely IP-dependent industries such as pharmaceuticals. This is why innovative medicine development is conducted in developed economies with strong IP rights regimes.

Excessive issuing of compulsory licenses on non-essential medicines will not help Thailand or any other country in boosting its attractiveness for FDI.

Thai prices down, African prices up

Thailand's compulsory licensing of medicines is clearly having a detrimental impact on its own country. Its actions will also have an on-flow effect for other countries inflicted with large populations of people infected with HIV/AIDS.

Thailand is not the wealthiest country in the world; but it is also not the poorest. Pharmaceutical companies invest millions to develop medicines and scale their prices dependent on the capacity of the market to buy these medicines. The cost of the investment is real. Each ARV can cost up to US\$500 million to develop.⁴²

Medicines sold in rich developed countries such as Australia and the United States are sold at a price much higher than in LDCs. This differential pricing structure is designed to ensure that the companies can recoup the cost of investment, while also recognising that essential medicines need to be provided at a reasonable price for consumers.

By undermining cost recovery through market segmentation, Thailand has acted to undermine the ongoing sustainability of providing affordable essential medicines to the world's poorest—particularly those in Africa.

Thailand is a middle-income country and attracts a mid-tier pricing structure as a result. Thailand has the capacity to pay modest amounts for medicines, those in Sub-Saharan Africa have a substantially decreased capacity to pay as much.

To take account of Thailand's actions, pharmaceutical companies will now need to redistribute lost revenue streams to the costs of people in other parts of the developing world.

An example from Europe demonstrates this well. In the 1990s 'parallel trading' (importing of goods currently available in a domestic economy) of pharmaceuticals occurred in the European Union as consumers tried to take advantage of cheaper prices in lesser developed EU members. The consequence was that prices rose in the lesser developed EU economies to compensate for losses in those engaging in parallel imports. Research showed that the differences in price gradually reduced from 30 percent to 10 percent.⁴³

Thailand is not alone. Brazil also recently issued a compulsory license for efavirenz. Both countries are mid-

tier economies with capacity to pay mid-tier prices. They are setting a bad precedent for other developing countries. If other mid-tier developing countries follow Thailand and Brazil's lead the cost of their short term benefit will be passed on to Africa's poor.

The 'other' non-patented medicines

By failing to enforce IP rights regimes, developing countries are also placing their HIV/AIDS patients at serious risk. Failure to enforce IP rights has brought about the rise of counterfeit medicines and breaches of trademark that place patients at serious risk. Flouting patents comes with risk, but at least true generics provide certainty for patients.

Counterfeit medicines make their way into the developed world, but their prevalence is highest in the developing world. The WHO has reported that up to a quarter of all medicines in LDCs are counterfeit.⁴⁴ The WHO defines counterfeit medicines as 'deliberately and fraudulently mislabelled with respect to identity and/or source'.⁴⁵

As outlined earlier, counterfeit medicines do not go through the same regulatory and quality hurdles applied to generic medicines to certify bioequivalence. The consequence is that they can often have insufficient or no levels of the active ingredients required by the patient.

In the process of breaching patents, counterfeit medicines often also breach trademarks and are branded as an innovative medicine. The consequence is that healthcare providers do not know if they are providing a counterfeit medicine, and subsequently transfer that risk to the patient.

Counterfeit medicines can lack the active ingredients necessary to assist a patient. The cost can be an increase in resistance and the need for a higher level of medical care and the costs that come with it.

Counterfeit medicines can also include toxic components or be delivered through inappropriate delivery systems. In Haiti 89 people died after ingesting counterfeit cough syrup that included anti-freeze. Similar incidents have occurred in Nigeria and Bangladesh. Estimates in China place the number of people who die from the use of counterfeit or sub-standard medicines each year between 200,000–300,000 people.⁴⁶

The costs of ignoring the real barriers to essential medicines through a fixation on IP rights are real. The interests of the world's poor cannot continue to be traded off while ideological NGOs campaign against IP rights.

Conclusion

Despite the rhetoric of NGOs, the real challenges facing access to essential medicines are not due to excessive protection of patents. IP protection plays a vital role in promoting innovation in public health. Undermining patents can actually have a detrimental effect on developing HIV/AIDS medicines for the world's poor. Moreover, weak property protections undermine the investment climate needed to promote the economic growth to fund the infrastructure to bridge the gap between medicines and their patients.

Enforcement of patent protections also combats the development and use of counterfeit medicines. These counterfeits pose immediate health risks. And they can breed and accelerate resistance to patented and generic medicines. This acceleration of resistance boosts the subsequent costs of HIV/AIDS treatment.

Thailand's military government has a questionable record of prioritising public health. Government spending in health has been woefully inadequate, particularly in light of significant pay increases for military officials and bureaucrats. Instead of addressing funding gaps due to unjustifiable government spending policies, Thailand has chosen to pass the blame to pharmaceutical companies.

Thailand and Brazil's recent issuance of compulsory licenses for HIV/AIDS and heart disease medicines will do little to promote access to affordable medicines. Instead their actions could hamper their own capacity to deliver medicines to their country's patients and also increase the costs for patients in poorer countries.

India provides compelling evidence that undermining patents doesn't yield improved access to affordable medicines. MSF's own numbers also make it clear that patented HIV/AIDS medicines needn't be cheaper than their generic competitors.

The focus on patents is also distracting policy makers from the real priority of decreasing the cost of essential medicines. Government duties, taxes and tariffs have a significant impact on the affordability of medicines. These government-imposed costs are a regressive tax on the world's poor and should be removed to promote improved access to medicines.

Inadequate infrastructure and reliable supply chains also provide an ongoing challenge for developing countries in meeting the medical needs of HIV/AIDS patients. Reckless compulsory licensing will undermine the investment environment necessary to promote the economic growth that can provide the capital to invest in improving this infrastructure and systems.

If NGOs are serious about improving the access to essential HIV/AIDS medicines of the world's poor, at the Sydney IAS Conference they should end their ideological campaign against IP rights and focus on the real barriers to affordable medicines.

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