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ANALYSIS

How Washington uses trade deals to protect drugs

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William Aldis was agitated. As the World Health Organisation's top man in Thailand, he knew Thai officials were hosting their US counterparts in the northern city of Chiang Mai to negotiate what to many outsiders might seem an entirely worthy objective: a bilateral free-trade deal. But he saw dangers – and decided to make his views public.

The "lives of hundreds of thousands of Thai citizens" would be put at risk if negotiators accepted Washington's demands for greater protection of drug companies' intellectual property rights, he wrote in an article for a Bangkok newspaper.

That was in January. By the end of March, Dr Aldis – just 16 months into what is normally a four-year tenure – was abruptly transferred sideways to a job in India, raising concerns in Thailand about US efforts to curb the independence of the WHO's public health professionals.

The spat highlighted the tensions generated by a US drive to strengthen patent enforcement and intellectual property rights protection around the world – a campaign backed by some of the powerful drugs companies that produce Aids medicines but opposed by many public health specialists, patient groups and developing nations.

On one side are those who argue that stronger patent protection will keep drug prices too high to meet the needs of developing-world patients. Pitted against them are others who insist innovation is under threat and the real problem in poor countries is a lack of hospital facilities and medical staff.

Widely discussed at last week's world Aids conference in Toronto, the issue prompted a petition signed by Médecins sans Frontières, the doctors' aid organisation, and dozens of other groups calling for a moratorium on free-trade provisions that threaten access to treatments. In it they demand that governments "protect the public from the potential negative consequences of bilateral and regional trade agreements on public health".

The controversy poses particular difficulties for the Geneva-based WHO, which is gearing up for the highly political election of a new director-general after the death in May of Lee Jong-wook. A WHO assembly is due to choose a successor in November

Dr Aldis, in his article published in the English-language Bangkok Post and entitled "It could be a matter of life and death", warned that the concessions sought by Washington could hinder Thailand's domestic production of generic drugs, particularly the life-saving medicines that will be needed to treat the 600,000 Thais living with HIV.

"The price of second- and third-generation HIV drugs will remain exorbitantly expensive," he wrote, adding that the Thai government – which has won accolades for its commitment to provide Aids drugs for all who need them – could thus find its public health system bankrupted.

After the article appeared, Kevin Moley, then head of the US permanent representation to the United Nations in Geneva, called on Dr Lee. Both verbally and in writing, he registered Washington's displeasure with the statements of the WHO's Bangkok representative.

One US official familiar with the discussions says: "For someone on the WHO payroll to criticise a bilateral negotiation is not appropriate."

Yet the subsequent abrupt transfer of Dr Aldis (himself an American) brought alarm in Thailand. "If outside political pressure can influence an organisation which is supposed to be dedicated to the health of the people, it is a really bad sign," says Jiraporn Limpananont, a pharmaceutical sciences professor at Bangkok's Chulalongkorn University and an expert on intellectual property rights. "It will be a threat for people all over the world, not just for

the Thai people."

At root, the dispute concerns US efforts to extend the patent protections laid down in existing multilateral trade pacts. Under the WHO's "trade-related aspects of intellectual property" (Trips) agreement, countries can override drug patents by issuing a "compulsory licence" to manufacture or import cheaper copycat versions, if they judge there to be a public health emergency.

But a congressional mandate urges the US trade representative to push for stronger protection of intellectual property rights around the world, through bilateral free-trade agreements (FTAs). After signing deals with small economies such as Oman, Jordan, Morocco and Bahrain, Washington has turned its attention to more significant trading partners such as Malaysia and South Korea as well as Thailand.

These efforts have been given added impetus by the expiry next year of the White House's "fast-track" trade promotion authority, which allows the administration to negotiate trade deals that Congress must then either approve or reject in their entirety. Last month's indefinite suspension of the WTO's Doha round of trade talks also refocused US attention on its bilateral trade deals.

In their talks with Thailand, echoing the terms of similar deals, US negotiators have demanded that the authorities agree to grant pharmaceutical companies "compensatory" patent extensions in the event of "unreasonable" delays either in granting drug patents or approving a drug for market use.

They have also sought five years of "data exclusivity", which would prevent makers of generic drugs using the clinical trial data, or other scientific information, from another company to prove the safety and efficacy of a medication after it comes to market. Such data protection would have particular repercussions for Thailand, where some Aids drugs were never patented, as companies previously judged the potential market to be too small.

Last, the US has pushed Thailand to adopt more specific language on the terms and conditions under which it would engage in compulsory licensing of new drugs, although Washington promised to issue a "side letter" clarifying that the binding language in the bilateral trade deal was consistent with the WTO's 2001 Doha declaration on Trips and public health.

Achara Eksaengsri, deputy director of research and development at Thailand's Government Pharmaceutical Organisation (GPO), says the bilateral conditions would have a highly detrimental impact on Thailand's ability to fulfil its pledge to provide drugs to Aids patients.

The Thai GPO is currently producing generic versions of older "first-line" anti-retroviral drugs for some 80,000 people and hopes to have 150,000 on treatment within two years. It also plans to provide generic "second-line" treatment using more sophisticated newer drugs for patients as required, an aim that would be hampered by conceding "data exclusivity" protection. "We have to plan how the government budget can support the Thai patients," she says.

In contrast, western pharmaceutical companies say that the protections are necessary to ensure they make adequate returns to encourage future research and development of drugs. They also argue that in the poorest countries most affected by Aids, they have made great efforts to help, offering discounted prices and waiving or not enforcing patents.

Harvey Bale, head of the International Federation of Pharmaceutical Manufacturers' Associations, says his members have been made scapegoats for far broader problems that have hindered the scaling up of Aids treatment in the developing world. "The issue is getting people access to drugs," he says. "We're still far short of the WHO's target of 3m on treatment by 2005 and the pledge for universal access by 2010. The basic problem is infrastructure, accessibility of trained medical staff, clinics and diagnostics."

American trade officials say the provisions they seek in their bilateral deals in Thailand and elsewhere will not impinge on health. "There is no evidence that the FTA has damaged access to drugs or the local pharmaceutical industry," says one. "Since signing its FTA with the US, Jordan has seen a big rise in the number of launches of innovative pharmaceutical products, while its own generics sector has thrived."

But Jordan has scant influence on the international pharmaceuticals market. The big clash relates to larger countries such as China, India and Brazil, which offer more lucrative potential markets to the drugs companies – but which also have important domestic generic industries that threaten to undercut western drugs companies

unless patent rules are toughened.

From their various perspectives, western drugmakers, generic producers and patient activists are all particularly focused on the recently developed second-line anti-retroviral drugs, still under patent. Demand for these is set to grow sharply in the next few years as patients develop resistance to their first-line therapies.

Under pressure from fledgling local pharmaceutical companies interested in innovation as well as international demands, India last year tightened its patent legislation. The previous generation of first-line Aids treatments had not been protected by patents, allowing companies such as Cipla and Ranbaxy to copy western drugs, offering them more cheaply in the developing world. For second-line drugs, that will be tougher.

A key test of the new regime is Kaletra, a drug developed by Abbott Laboratories of the US. The company has already clashed fiercely with Brazil, which last year threatened to issue a compulsory licence so the state-owned pharmaceutical company could produce Kaletra. That was out of concern that purchases for its ambitious Aids treatment programme would otherwise be too expensive.

“We are supportive of the Trips legislation but we view intellectual property as at the core of what we do,” says Jennifer Smoter from Abbott.

Pedro Chequer, head of Brazil’s national Aids programme at the time, says government officials were subjected to intense lobbying at the highest levels: “I was told of meetings, phone calls from the Senate, Congress and the White House, with threats of direct retaliation.”

The office of Brazil’s President Luiz Inácio Lula da Silva eventually backed away from issuing a compulsory licence, in exchange for Abbott’s agreement to a six-year contract offering the drug at a lower price while preserving its patents.

That is precisely the type of deal that could be compromised by FTAs. “Compulsory licensing is a weapon,” says one trade expert. “Developing countries can say: ‘We are going to make this unless you cut your price.’ It’s a good weapon to use – that itself is a worthy thing to have.”

Dr Achara says Thailand may request a compulsory license in three or four years’ time for Kaletra for the Thai GPO. But a Thai-US bilateral trade deal – talks on which are on hold, probably until after October, when the country is scheduled to rerun its general election – would weaken her hand, she fears.

Mr Bale warns that overriding patents may bring unintended consequences. He suggests that the price, quality and capacity of local manufacturers may not meet the objectives sought. Conversely, Jim Kim, a former head of HIV/Aids at the WHO and still active in combating the disease, says: “The pharmaceutical companies are saying it would be better for countries to use their discounted price schemes. But we’re already hitting supply problems, while demand for the drugs is growing steadily.”

In practice, compulsory licences have so far been issued rarely and showdowns with countries where FTAs cover pharmaceutical products have not taken place. Furthermore, US policy is not entirely clear cut.

Even Jamie Love, a veteran critic of the US campaign for tougher intellectual property rights abroad, says: “There’s no doubt the bilateral agreements are designed to step back from Doha, making it harder to introduce generics. But it’s hard to say the US position is crystal clear. It depends who’s on the ground.”

While US trade representatives push for tough patent rules in the interests of national pharmaceutical manufacturers, for example, Washington regulators at the Food and Drug Administration recently began approving foreign-made generic copies of anti-retrovirals. That allows for their purchase – at the expense of higher-priced US-made drugs – by Pepfar, President George W. Bush’s Aids fund for the developing world, which is under pressure to escalate treatment cost-effectively.

Still, as the burden of Aids continues to grow, so will the tensions between developed-world manufacturers and budget-stretched developing nations. One place where the debate will be played out is at the WHO.

Dr Lee, a cautious man, was wary of antagonising the US, to which he owed his election three years ago. In the contest to replace him, the candidates may find reconciling drug affordability and intellectual property to be among

the trickiest stances on which they will campaign.