



Thailand and the Drug Patent Wars

By Roger Bate

Middle-income countries with large HIV-positive populations have led the charge to secure cheaper drugs by using strong-arm tactics against Western pharmaceutical companies. What started with Brazil and continued in India¹ has now spread to Southeast Asia. Thailand is going further than Brazil ever did and is breaking patents on a heart disease drug as well as HIV drugs. Thailand claims that this action is to support its goal of making high-quality medicines available to patients on a sustainable basis, but it has lowered its health budget, belying this claim. The damaging practice of breaking patents will harm Thai patients as the research-based industry withdraws from the country, resulting in less investigation of drugs that respond to resistant strains of diseases. It will also harm patients worldwide, as lower revenues for drug companies mean less funding for development of new drugs and fewer incentives to introduce new drugs in the developing world.

Thailand is the only country in Southeast Asia never to have been ruled by a European power. Though its political history since 1932 has been marred by numerous coups, its economy averaged over 9 percent annual growth in the decade before 1996.² An influx of workers providing cheap labor, an abundance of natural resources, and pro-investment and export-led policies contributed to Thailand's economic success in the boom years leading up to 1997. The Asian financial crisis caused a brief Thai recession, but the country quickly recovered and became one of "East Asia's best performers" in 2002. Thailand's economy grew consistently at over 5 percent per year, even overcoming the impact of the 2004 tsunami.³

Yet on September 19, 2006, military leaders led by army chief Sonthi Boonyaratglin staged a coup, ending the allegedly repressive and autocratic rule of then-president Thaksin Shinawatra. According to various reports by the Asian Human Rights Commission (AHRC), Thaksin's abuses, including human-rights violations and the manipulation of

the media, were manifold. But the AHRC considers Boonyaratglin's military junta to be far worse than Thaksin's civilian autocracy. Within hours of taking power, the army abrogated the constitution and authorized censorship. It has since instituted currency controls and new foreign-ownership laws. Condemning the coup, the AHRC writes, "Thailand is today without a constitution and without the rule of law."⁴ It is perhaps not surprising, then, that Thailand's government is violating World Trade Organization (WTO) rules on patents.

On January 25, 2007, Thailand's interim government issued compulsory licenses—which require manufacturers to license generic versions of their patented drugs—for two Western medicines: Kaletra, an advanced anti-AIDS medicine manufactured by Abbott; and Plavix, a blood-thinning treatment to help prevent heart disease, produced by the France-based Sanofi-Aventis and U.S. firm Bristol-Myers Squibb. These attacks were preceded in November 2006 by a violation of Merck's patent on the anti-AIDS drug Stocrin.⁵ The government threatened to break patents on eleven more drugs.⁶ Explaining the rationale behind Thailand's decision, health minister

Roger Bate (rbate@aei.org) is a resident fellow at AEI.

Mongkol Na Songkhla said that “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.”⁷

The WTO’s Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) clearly states that under a compulsory license, a government can produce the needed drug itself or authorize a third party to do so. While each WTO member is free to determine the grounds under which such licenses are granted, it is generally understood that compulsory licensing should be confined to “public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics,” which represent a “national emergency or other circumstances of extreme urgency.”⁸

The “need” for Plavix does not constitute a “national emergency,” nor is Plavix an “essential medicine” as defined by the World Health Organization (WHO). Less than 1 percent (about 300,000) of the Thai population suffers from chronic coronary obstructive disease.⁹ Thailand’s decision has very little to do with public health emergencies and much more to do with the country’s economic and political priorities.

Thailand’s Health Industry: Stingy, Corrupt, and Derelict

But what of the health minister’s claim to lack the money to purchase brand-name drugs? While Thailand is not wealthy by Western standards, it is not poor either. With a 2006 per-capita GDP of \$9,100¹⁰ and the second-largest economy in Southeast Asia, Thailand can afford to pay more for AIDS medicines than most countries in the region and many countries in other parts of the world. The AIDS epidemic in Thailand, largely fueled by its notorious sex industry, is on par with Brazil’s.¹¹ There are approximately 500,000 HIV-positive people in Thailand out of a total population of 64.6 million.¹²

Like other middle-income countries,¹³ Thailand enjoys a “mid-tier” drug pricing status, which means that the Thai government pays less for HIV drugs than European or U.S. consumers, but more than most African governments. One company, Merck, even sells HIV

medicines to Thailand at Africa-level prices because of Thailand’s significant HIV problem.

Furthermore, although the government claims poverty, the country’s military leaders awarded themselves pay increases totaling \$9 million and increased the defense budget by over 30 percent, a \$1.1 billion hike.¹⁴ This was done at the expense of funding for its health sector, which informed sources say is dropping from an already low level. Thailand’s total expenditure on health care in 2003 was 3.3 percent of GDP.¹⁵ Compared with the expenditures of other middle-income countries such as Brazil (7.6 percent) and China (5.6 percent), this is a modest allocation.¹⁶ In contrast, even poor African countries such as Tanzania and Namibia spent significantly on health care in 2003, 13 and 12 percent, respectively.¹⁷

Thailand’s Ministry of Public Health (MOPH) intends to make the three patented medicines—Stocrin, Kaletra, and Plavix—available to the Governmental Pharmaceutical Organization (GPO), a state-owned, profit-making enterprise that competes (on price but hardly on quality) with generic and research-based companies. If GPO profitability is bolstered because of the compulsory licensing, this will probably violate TRIPS rules, which state categorically that compulsory licensing must not be invoked for commercial gain.

The GPO’s track record of corruption is well-documented. In 2002, Thai auditor-general Jaruvan Maintaka reported that the GPO had stolen approximately \$13 million from the government over the previous four years.¹⁸ Her report also noted that “[t]he GPO sold about 60 percent of its medical products to government agencies at above market prices. In some cases, products were marked up 1,000 percent.”¹⁹ The report goes on to say that the GPO still has many defects which are not being addressed, and may even be exacerbated, by its rapid expansion, giving officials the chance to reap personal benefits.²⁰ Occupied with copying Western medicines, the GPO has had little interest in channeling money toward the innovative division of its drug industry. In 2005, with profits of over \$35 million, the GPO only reinvested a negligible 2 percent of its profits in research and development (R&D).²¹

If the Thai government aims to improve universal access to essential drugs, it is counterproductive for the

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government to maintain its 10 percent tariff on most drug imports and its 7 percent value-added tax on all medicines. Various studies have shown that tariffs on drugs tax the sick,²² limit access to drugs, and can be removed without adverse effects on a country's tax revenue base.²³

But it appears that the real aim of the Thai government is less to provide "universal access to essential medicine for all Thais"²⁴ and more to spend less on health care. Since 2001, over 78 percent of Thailand's population has been covered under the Universal Coverage Scheme, a free public health system financed solely by the government.²⁵ But the military government does not seem willing to invest the financial resources needed to maintain it. It *does*, however, want to strengthen potential profit centers, one of which is domestic drug manufacturing. As government officials noted, "the ultimate goal . . . is to improve the potential, capacity, and competitiveness of the local industry."²⁶

Patent-Breaking's Public Health Risks

The criticisms of the GPO go beyond its corruptive tendencies and its pursuit of ill-gotten profits to encompass graver public health concerns. First, the GPO facilities for manufacturing HIV treatments have not passed WHO's relatively weak manufacturing standards. WHO approves manufacturing facilities after an inspection of a single product—often an antibiotic or aspirin, which are simple to produce. This approval does not certify that the facility is capable of producing all drugs, especially the most complex types such as HIV drugs. Nevertheless, the GPO failed to meet even WHO's minimal standards in every category attempted. More specifically, bioequivalence data on the quality of GPO-manufactured drugs are not available. This suggests that drugs produced by this industry are, at best, inferior copies—not generics which represent drugs that are bioequivalent or pharmaceutically equivalent in composition and performance to their branded counterparts.²⁷

Second, GPO products are not prequalified by WHO. Viruses mutate, especially HIV, and become resistant to even the newest treatments, which is why the WHO convened a technical review consultation group to study the efficacy of existing drugs. The meeting yielded a WHO Prequalification List which "guarantees" the quality and efficacy of certain drugs as well as lists the names of the drug companies whose manufacture of the drug is approved. WHO has received well-deserved criticism for this process,²⁸ but it appears

to have improved recently, and GPO drugs are absent from its list.

Since GPO drugs are probably poor copies, their widespread use will increase drug resistance in the Thai population. Lembit Rago, WHO's coordinator of quality and safety, put it starkly:

Nobody would buy an airplane without wings. . . . Drugs should be treated the same way. But with drugs, it's difficult to understand what makes them up to a certain standard of quality because there are so many elements involved. In certain cases, minor things are wrong, and in some, major things. Drugs that are not WHO pre-qualified may not directly kill people, but they could foster resistance to AIDS drugs.²⁹

Drug resistance is inevitable, but it is likely to be worse in Thailand than many other places because of low-quality drugs and a modest health-care infrastructure. All evidence from Thailand points to this real and emerging problem. An estimated 108,000 of 500,000 people living with HIV/AIDS depend on GPO-vir, the copy version of the first-line antiretroviral therapy produced by the GPO. Twenty thousand of those treated with it—almost one-fifth—have already developed resistance to the drug.³⁰ These results complement those of a 2005 study from Thailand's Mahidol University, which found that for a group of 300 patients sampled for the resistant-inducing effects of GPO-vir, between 39.6 percent and 58 percent showed resistance to it.³¹ Western drugs may be more expensive than copies, but their high quality limits drug resistance and treatment failure.

Drug resistance can be controlled by monitoring drug failure and switching products, but this is not happening in Thailand. New drugs will inevitably be required, regardless of oversight. The industry must have incentives to commit the time—most new medicines take over ten years—and the hundreds of millions of dollars required to successfully bring a single new product to the market.³² Companies must therefore be able to price above the marginal cost of pure production in all but the poorest markets, which no longer include increasingly wealthy and large Asian markets. Thailand is just one country, but if pharmaceutical innovators cannot realize even minimal returns in Thailand, current pricing structures and future R&D will be undermined. These effects will be even more pronounced if other countries follow Thailand's lead.

Thailand's Decision: Actions and Reactions

Thailand's decision to break patents was applauded by well-known anti-intellectual property activist groups and some charitable foundations. Médecins Sans Frontières (MSF, known in English as Doctors Without Borders) led the way, saying: "Thailand is demonstrating that the lives of patients have to come before the patents of drug companies."³³ The William J. Clinton Foundation also offered its ringing endorsement for what it calls Thailand's "measured use" of compulsory licenses to ensure more affordable access to high-quality drugs, adding:

Compulsory forms of licenses represent an additional tool for ensuring affordable access to medicines, which may be particularly appropriate in cases where the patent holder has not taken steps to offer affordable pricing or to issue voluntary licenses.³⁴

The insinuation is that drug companies profit at the expense of public health. But is this true? The industry points to its direct negotiations and efforts to lower prices. For example, all three companies affected by Thailand's patent-breaking have a long-standing relationship with Thailand's health ministry, and producers of HIV medicines have discounted these drugs for the Thai government over the past five years. As Douglas Cheung, managing director of MSD (an international subsidiary of Merck) in Thailand, notes in a 2005 letter to MOPH:

Since March 2001, Merck and its MSD subsidiaries across the world have implemented a policy to offer Stocrin . . . at nonprofit prices to developing countries . . . [and] that includes Thailand. I assure you that our corporate goals and policies regarding pricing of Stocrin . . . in Thailand are in line with providing optimal ARV access to HIV patients.³⁵

Company representatives have tried recently to engage MOPH in negotiations, to no avail. The Thai

government says there is little point in negotiations, since only the *threat* of issuing compulsory licenses leads to lower prices.³⁶ MOPH has a point: after every threat from Brazil to issue compulsory licenses, many—if not all—affected companies have indeed lowered their prices. But companies have also lowered prices without the threat of patent seizures. For example, Abbott and MSD unilaterally reduced the prices of their HIV medicines in 2006, a year prior to the Thai government's first action against Western patents.³⁷ So the Thai position is far from incontestable. Furthermore, threats to Western investors are poor methods of encouraging more foreign investment, since it signals a hostile environment to the wider business community.

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In the absence of dialogue, a virulent standoff—and even escalation—is emerging between the Thai government and the Western drug companies. Soon after Thailand's decision, Abbott responded by choosing not to launch any of its new medicines in Thailand, although this decision would not affect drugs already on sale in Thailand.³⁸

What is noticeable about this whole affair is the coordinated condemnation of any public official who voices legitimate criticisms of the Thai government's actions. During a visit to the National Health Security Office in Bangkok, WHO director-general Margaret Chan cautioned Thailand: "I'd like to underline that we have to find a right balance for compulsory licensing. We can't be naïve about this. There is no perfect solution for accessing drugs in both quality and quantity."³⁹ Within hours of her remarks, Chan was criticized by various civil society

groups and humanitarian organizations. Ellen 't Hoen, policy director of MSF's Campaign for Access to Essential Medicines, said: "It is not the role of the WHO to protect the interests of the pharmaceutical companies."⁴⁰ Nimit Tienudom, president of the Aids Access Foundation, called Chan's position "disappointing. The organization should have supported drug access and promoted the study of inexpensive drugs for the sake of the global population rather than supporting pharmaceutical giants."⁴¹ This led to an apparent retreat by Chan, who wrote to the Thai government to explain that her remarks had been misinterpreted: "I deeply regret that

my comments . . . were misrepresented in the media, and may have caused embarrassment to the government of Thailand. They should not be taken as a criticism of the decision of the Royal Thai government to issue compulsory licenses.”⁴²

Yet Chan’s original remarks were not a ringing endorsement of the pharmaceutical companies’ position per se. She simply stressed the importance of communication to evaluate the local and global impact of Thailand’s decision on HIV treatment and drug innovation. The simple truth, one that she is all too aware of, is that drug access and innovation must go hand in hand. When countries choose to adopt compulsory licensing as a “valid form of cost containment, a de facto pricing and reimbursement (P&R) measure”⁴³ while sidelining intellectual property rights, it eventually undermines drug access. As the countries of Asia and Latin America develop economically, they must (from standpoints of both equity and efficiency) pay more of the R&D bill than they do now. The GDP of Thailand is over ten times greater than that of the poorest countries in Africa, but it wants Africa-level prices for HIV drugs. Competition and tough negotiation are fine, but free-riding on Western patients is neither fair nor sensible. Thailand could end up with cheaper drugs now at the expense of having access to fewer new medications in the future.

So far, there has been little conciliatory action on the part of the Thai government. Suwit Wibulpolprasert, a senior economic adviser to the health minister, went so far as to argue that Thailand and other developing countries should prevent foreign nationals from leaving their country in the event of a bird flu pandemic until and unless developed nations share their stockpiles of vaccines and antivirals.⁴⁴ No one really believes that the Thai government would detain U.S. tourists until the Bush administration sent vaccines, but such overheated rhetoric is harming Thailand all the same.

A U.S. Chamber of Commerce survey of 234 business executives from five continents showed that Thailand’s new economic and health policies and poor intellectual-property safeguards could be jeopardizing international investment in the country.⁴⁵ Teera Chakajnarodom,

president of the Pharmaceutical Research and Manufacturers Association, the lobby for the Western drug industry in Thailand, recently announced that leading members of her association have confirmed that “further investment in Thailand will be put on hold . . . [as] . . . the government cannot provide a basic guarantee for the safety of their assets.”⁴⁶ The U.S. Trade Representative is undoubtedly watching Thailand, and probably contemplating action against the country.

The Road Ahead

As the countries of Asia and Latin America develop economically, they must pay more of the R&D bill than they do now. The GDP of Thailand is over ten times greater than that of the poorest countries in Africa, but it wants Africa-level prices for HIV drugs.

There are several directions in which the current patent battle can go. With continued escalation, more drug patents will be broken and fewer new drugs will be available in Thailand. Under a sort of détente, the drug companies will lower many prices and the Thai government will issue no fresh threats. The third option calls for the Thai government to reverse its decision and back down entirely.

The first seems the least likely. The Thai health ministry initially threatened fourteen drugs but seems to have settled on three, of which only one is truly contentious (Sanofi-Aventis’s heart drug, Plavix), since few would argue that heart disease is an emergency. Furthermore, U.S. business leaders are becoming increasingly concerned, and active, in opposing Thailand’s policy of patent piracy, and broader Thai interests will probably force it to accept U.S. action (if not rhetoric) over the narrow priorities of

MOPH. The second outcome is the most likely, since both sides can claim some level of victory, and the nervous lawyers within the companies are likely to sue for peace before a total drug-company victory (the third option) is possible, which is something of a shame because a Thai retreat is possible.

The advisers to MOPH have miscalculated. Their war against Western patents has only a half-hearted champion in the Thai military government. Members of the junta want to feather their own nests, expand military spending, and reduce health spending, but they are not going to risk billions of dollars in U.S. trade for the sake of a few million dollars.

In the long run, the patent battle in Bangkok could be a tipping point—the last time that a middle-income country takes belligerent action. Unilateral aggression such as the Thai patent-breaking does not lead to better health or wealth generation; it simply means international friction, poorer drugs, and lower health standards in the domestic market. Activists deserve praise for pressuring companies to lower prices and encourage competition, but they have gone too far in Thailand, and they may pay for it. There is no sign that the military leaders are about to relinquish power. The activists' blind opposition to patent protection has left them supporting a military government at the expense of the health of the Thai population.

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Notes

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