Finding a middle ground

Edward Kelly and **Franck Fougère** debate the merits of Thailand's programme of compulsory licensing for pharmaceutical patents.

Question: Was the Thai government right to begin issuing compulsory licences for pharmaceutical drugs in 2006 and was the way in which the programme was carried out legal?

Edward Kelly
Siam Premier and LGP Asia

According to the World Health Organisation, Thailand is a middle-income country with impressive achievements in both economic and social development. The Kingdom has a long and successful history of health development, achieving universal health care for Thai citizens in 2002, vibrant primary health care and innovative health system development and health promotion.

Notwithstanding dramatic improvement in Thailand's export-led economy over the past three years, Thailand maintains that it is necessary to continue its compulsory licence policy stripping pharmaceutical companies of private property rights to patents covering several medicines. The rationale for the policy is stated to be a general lack of available funding to pay for the medicines produced by R&D-based pharmaceutical companies.

Pay rises, but not for patients

On December 14 2010 the Thai cabinet approved an across the board pay raise for all state workers and political office appointees of 5%, while parliamentarians received hikes of 14.3% to 14.9%. This B13 billion ($432 million) raise for state officials and senators is presumably part of the roughly B2.07 trillion ($64.7 billion) budget for the current fiscal year, which began on October 1. The budget bill passed by Parliament represents an approximate 22% increase from last year.

Thailand's healthcare expenditure between 2007 and 2010 has been between B280 billion and nearly B300 billion ($9.3 billion and nearly $10 billion). While healthcare spending has remained fairly stable, spending on other national priorities, such as defence (approximately 8% of the overall budget) has increased significantly since late 2006, when the coup d'état occurred (and also when the compulsory licensing policy was first rolled out). Some have questioned how pay hikes for government officials are possible when the government seems to contend that there is not enough funding to buy medicine for Thai people.

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The GPO monopoly

The compulsory licensing policy was invoked by the Ministry of Public Health based on the so-called "government use" exception of the Thai Patent Act, which would allow a patent to be broken for purposes of "public non-commercial use" of the

One-minute read

At the end of 2006 Thailand's military government began a programme of compulsory licensing for anti-AIDS drugs that inflamed the debate over patents and access to medicines. The programme was expanded in early 2007 to include another AIDS drug and the blood thinner Plavix. Since then the licences have received little coverage, but they have remained in place. It is looking increasingly likely that applications for compulsory licences will be made in India by generic drug companies or patient groups. Managing IP asked two IP lawyers with extensive experience of advising drug companies to debate the legality of the issue, and whether it was right to begin the programme. Although differences remain, the protagonists are able to find a surprising amount to agree on.

patented invention. Although legally restricted to non-commercial use, the primary beneficiary of the policy has been the state-owned Government Pharmaceutical Organization (GPO), which, paradoxically, is a for profit organisation. Business has been booming for the GPO since the compulsory licensing policy went into effect. According to its annual report, the GPO has generated net profit averaging more than B1.1 Billion ($37 million) since 2007, a substantially improved performance from 2004 to 2006 before the policy began.

Use by the GPO of patents owned by private R&D based pharmaceutical companies to buy generic products from India and sell those products for its own gain has raised questions about the legitimacy of the policy. Thailand's Patent Act must comply with TRIPs, which allows compulsory licensing in exceptional circumstances.

In the extraordinary case where a compulsory licence may be justified, TRIPs Article 31 requires: that the public use must be non-commercial; that a royalty be paid to the patent owner as adequate remuneration, taking into account the economic value of the authorization; and that the legal validity of any licence be subject to judicial review or other independent review in the Courts.

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In Thailand's case, GPO is arguably using the compulsory licences in a commercial manner for its own account. It has not paid any royalty to affected patent owners and has not even agreed on the rate to be offered much less paid (at least in the cases with which I am familiar). Finally, none of the patent owners have been afforded any right to challenge the legality of the compulsory licence in the Courts. Indeed, Thailand's position is that a patent owner may only challenge the rate of royalty imposed and cannot test the merits of the licence itself.

TRIPs and respect for IP

TRIPs also requires that, even if the compulsory licence were justified because of exigent circumstances at the time it was invoked, the licence should be discontinued when those circumstances no longer exist. Thailand is flush with cash: the currency and stock market are at long-time highs, exports continue to impress and foreign reserves are at unprecedented levels. Whatever funding crunch may have justified the licences in 2006 after the coup has long since disappeared.

These facts lead many to question whether the compulsory licensing policy has been implemented by the Thai government in a manner consistent with a TRIPs-compliant interpretation of the Thai Patent Act. Unfortunately, any rational discussion of whether executive authority has been abused is immediately drowned out by activists shouting canned slogans about profits over patients. This is a guerrilla tactic that completely obscures the real policy issues involved.

From the standpoint of national competitiveness, is there any merit to continuing the compulsory licensing policy? In some cases, the licence has been imposed even when a non-infringing generic substitute is already available on the market. If a generic substitute can be purchased without having to break a patent, you could argue that the compulsory licensing policy is not driven at all by concerns related to assuring access for patients, since access has already been assured. Moreover the continuation of compulsory licensing will only serve to highlight the question of intellectual property risk for foreign investors, calling into question Thailand's commitment to respect for IP and making the country a less attractive destination for high tech investment.

Substituting supply of medicines from India certainly improves competitiveness for India, in terms of increased stature, more employment and more tax revenue for the economy. What needs to be examined is whether there is any comparable advantage to the Kingdom of Thailand in depriving a heavily invested tax-paying Thai employer engaged in an important industrial enterprise of its ability to generate a return on its investment in Thailand.

The time may have come for a calm, clear-eyed and rational reconsideration of the necessity of the Thai government's policy on compulsory licenses.

Franck Fougère
Ananda Intellectual Property

Emerging economies have become very attractive markets for pharmaceutical companies. While North American and European markets are saturated and highly regulated, South America and Asia (including China and India) represent a new frontier promising a high return on investment. Innovative and generic medicines manufacturers have been eyeing these markets for various reasons:

In emerging countries, healthcare is financed largely out-of pocket (up to 60% in Asia) and the number of middle-class consumers is rapidly increasing;

Governments and health authorities intervene less, which means fewer regulations and less demand for transparent drug pricing, as well as easier drug registration procedures;

The cost for producing, developing and commercialising old and new drugs is significantly lower than in traditional markets because of cheaper patent protection, lower production and drug registration costs, cheaper logistics and proximity to producers of active pharmaceutical ingredients;

Emerging countries have a rich biodiversity and traditional knowledge which may help with the development of new drugs and methods of treatment;

Emerging markets are plagued with a triple disease burden of so-called "old diseases" like tuberculosis and malaria, diarrhoeal diseases and malnutrition as well as new infectious diseases like Influenza A (H1N1), and a silent pandemic in the form of non-communicable diseases such as diabetes and cancer.

A recent study predicts that sales in 17 so-called "pharmerging" countries – including Thailand – will "in aggregate expand by $90 billion between 2009 and 2013". In the history of pharmaceutical industry this is unprecedented.

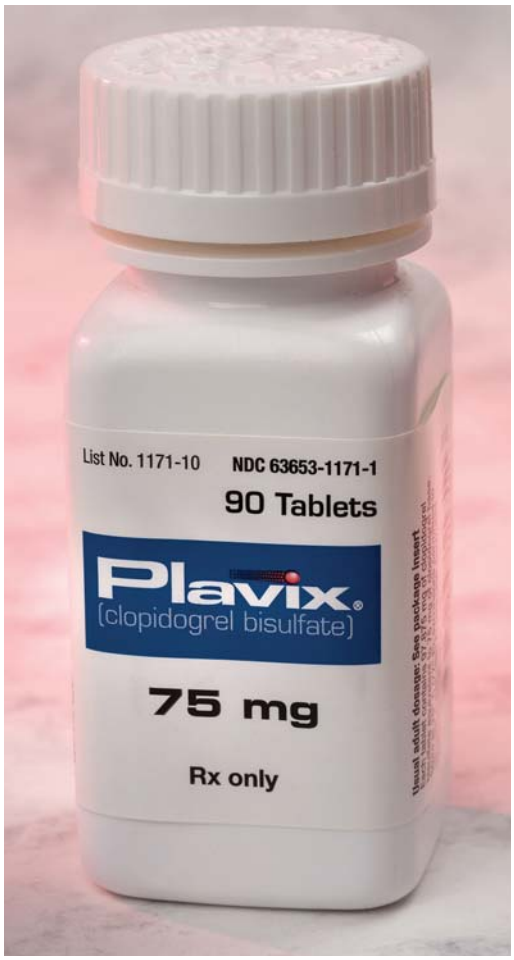
Civil society and international Non-Governmental Organizations (NGOs) are now using these figures to push for greater access to affordable medicines especially in poor and emerging countries. "Of all the issues discussed at World Health Organisation governing bodies, access to medicines

consistently sparks the most potentially explosive debates," Margaret Chan, Director General of the World Health Organization (WHO) has stated.

In Thailand, NGOs such as the Thai Network of People with HIV/AIDS, the Social Network for Cancer Patients, AIDS Access Foundation, Foundation for Consumers, Médecins Sans Frontières and Oxfam were strongly lobbying the Thai government to issue compulsory licenses.

High prices

The main reason for Thailand to resort to compulsory licensing in 2006 and 2007 was because of the prices of original drugs which were perceived as extremely high. At that time, the rationale for granting the licences was that more patients would be able to afford high quality medicines if the costs were lowered.



Government statistics show that these two goals were achieved. Compulsory licensing is said to have already saved B1.18 billion baht ($40 million) on the purchase of anti-retroviral drugs and the total cost savings accrued to the Thai government is estimated at B7 billion ($233 million) for the period 2006 to 2011. In addition, Thailand's compulsory licensing has forced down the prices of efavirenz and the lopinavir-ritonavir combination by 3.4 and 6.4 times respectively since the country announced its policy on HIV/Aids and cancer drugs in November 2006.

Regarding patient access to drugs, before the compulsory licensing of the two drugs, about 4,539 HIV-positive people had access to efavirenz and only 39 could afford the lopinavir-ritonavir combination. Compulsory licensing resulted in an increase in the number of patients receiving efavirenz to 29,360 and more than 6,200 people now receive the lopinavir/ritonavir combination.

The Health Intervention and Technology Assessment Project found that compulsory licensing made drugs available to an additional 84,000 patients, half of whom needed the widely used heart drug, clopidogrel (Plavix)

TRIPs and transparency

From a legal perspective, Thailand clearly interpreted the rather vague conditions of the Doha Declaration (which allow a country to issue a compulsory licence in the case of a public health emergency for the production of generics without the consent of the patent owner), Article 31 of the TRIPs Agreement and its own legislation – the Thai patent Act BE 2522 (AD 1979) – to justify the resort to compulsory licensing.

Section 51 of Thai Patent Act allows government to grant a compulsory licence under specific conditions including "to carry out any service for public consumption"._Section 51 further includes a paragraph regarding the royalty to be paid to the patentee or his exclusive licensee, a condition explicitly required by Article 31 of the TRIPs Agreement. In fact the Thai government did propose a royalty rate of 0.5%, which was supposedly rejected by some affected patent owners as they considered it arbitrary and too low compared to other countries.

Greater transparency is needed. It is needed now and over any future compulsory licences. Negotiations with affected patent owners should be made transparent before any compulsory licensing decision is made. In addition, clear selection criteria for choosing a drug should be developed and incorporated into the Thai Patent Act or its Regulations.

On the issue of whether the compulsory licensing policy has been implemented in a manner consistent with the TRIPs Agreement, the patent owners affected may not want to bring a case in Thailand. Thai public opinion is generally in favour of the licences and supportive of local manufacturers of generic medicines in Thailand.

On top of the guerrilla tactics mentioned Edward Kelly, there is also a nationalistic aspect. A recent study points out that from 1999 to 2006 out of 29 pharmaceutical companies manufacturing in Thailand only 12% conducted R&D activities and all these companies were wholly owned by Thai nationals. Bringing a case in Thailand could create a precedent which may not be in favour of the affected patent owners.

Reassessing the GPO

What needs to be addressed and reviewed in Thailand in our view is the role of the GPO. The issue is not so much whether GPO role is for profit: GPO's profits are supposed to be used for the public good, such as to produce medicines in response to emergency situations like the influenza pandemic and produce orphan drugs. The real issue is that GPO, now the largest domestic drug manufacturer, has a near monopoly over the public hospital sector in the country. Public hospitals are legally obliged to purchase 80% of their drugs from the GPO. Drug manufacturers are starting to realize that the monopoly enjoyed by GPO is not fair competition and is potentially preventing new drugs (including generic drugs) from being commercialised in Thailand.

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Generic drug manufacturers are becoming more hesitant to enter the Thai market or to develop a new generic drug locally as GPO might produce a similar product and benefit from their near monopoly. Interestingly, the dominant position of GPO could undermine the efforts of Thai authorities to develop their generic drug market, increase their dependency on branded medicines and ultimately reduce access to affordable medicines for the consumer.

Edward Kelly

Franck and I share common ground on many points, particularly in relation to the role of the GPO and whether GPO's monopolisation of the Thai market will have positive or negative long-term consequences for Thai patients.

But a few facts should be clarified. Thailand is not a poor country – it is a middle-income country, according to the most recent World Bank rankings. Moreover, Thailand's healthcare system is publicly financed for Thai people according to the Kingdom's universal healthcare scheme, which is constitutionally mandated. Thai people will not pay less or more for drugs under compulsory licences; the savings goes to the government, minus the profit taken by GPO on sales of the drugs in question.

That more patients are receiving efavirenz, lopinavir/ritonavir and clopidogrel now than had been receiving the medicines in 2006 is also not disputed. Firstly, more Thai sufferers of HIV have become resistant to GPO's first line medicine – GPO-vir – a laudable product produced at low cost by GPO, but one which comes with an unusually high rate of resistance, raising questions about the quality of the medicine.

What should be noted is that the claimed savings attributed to the compulsory licences are over-stated in two respects: first, all three companies losing patent rights under the licensing scheme offered pricing and capacity building packages that were very competitive compared with the packages offered by generics producers, but the savings are calculated based on advertised market pricing; more importantly, economic savings may come at an even greater cost to patients in terms of quality. If a first-line therapy produced by the GPO such as GPO-vir can lead to alarmingly high resistance rates, as studies by Mahidol University have shown, do we really want to risk having second-line therapies being produced by GPO or its Indian suppliers? There are no third-line therapies.

The research based pharmaceutical industry does not oppose appropriate use of compulsory licensing provided that such use is in line with the provisions set out in the TRIPs Agreement. There can be no argument that extensive use of compulsory licenses will undermine IP rights and negatively impact the ability of research-based pharmaceutical companies to discover and develop new medicines.

Compulsory licensing has turned out to be an enormous and divisive distraction. Governments, healthcare advocates and academics need to work in collaboration with the pharmaceutical industry toward a common goal – building a system that is accountable to all stakeholders and that continues to produce medicines that help us to live longer and better lives.

Franck Fougère

The time has come for Thailand to assess and publicly debate whether its compulsory licensing policy has been the right decision. While it may have been compliant with the TRIPs Agreement and positive developments have occurred, its implementation may legitimately be a cause of concern especially since the GPO is thought to be considerably benefiting from it.

Legal and economic arguments should be taken into account carefully when assessing the legitimacy of compulsory licensing in Thailand. While I do agree with Edward that Thailand is not a poor country, global rankings showing the level of development of a country should not decide whether or not compulsory licensing is legitimate or not. Thailand's economic growth is very poorly distributed. Millions of people in Thailand especially in country areas such as in the north-east lack access to cheap and safe medicines. I am sure Edward, who has been in Thailand for more than a decade, fully agrees with me on this.

In conclusion, Edward's last words that "Compulsory licensing has been an enormous and divisive distraction" are absolutely true. Attention should not be diverted from serious issues such as drug resistance, access to medicines and poor-quality medicines. It is also time on a global scale to acknowledge that TRIPs and its flexibilities (such as compulsory licensing) are clearly not sufficient to enable poor countries (and even middle-income countries such as Thailand) to address these serious issues.

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