

Thailand Responds to Compulsory License Critics

The government of Thailand has issued a report to answer questions raised by the public and the pharmaceutical industry about its recent decisions to suspend patent protection for three drugs used to treat AIDS and heart disease.

The white paper follows months of intense debate that has pitted health care activists against major pharmaceutical companies over the government's decisions to issue compulsory licenses for the production and import of generic versions of Merck's Stocrin (efavirenz), Abbott Laboratories' Kaletra (lopinavir/ritonavir) and the heart drug Plavix (clopidogrel) jointly marketed by Bristol Myers Squibb and Sanofi-Aventis (Bridges Year 11 No.1 page 17).

The compulsory licenses allow Thailand to import, distribute and sell generic versions manufactured in India, where the three drugs are not patented. The generics will be produced locally when the state-owned Government Pharmaceutical Organisation has the capacity to do so.

Pharmaceutical industry sources have complained that the government suspended the patents without adequate prior negotiations with the patent holders, and have warned that the compulsory licensing decisions may induce companies to decline making new innovative medicines available in Thailand. Indeed, Abbott announced in March that it would not introduce new medicines there and withdrew all pending marketing approval applications.

Why Were the Patents Suspended?

The white paper explains that the compulsory licences are necessary to achieve universal access to essential medicines, as mandated under the National Health Security Act of 2002. Thai citizens are covered by public health insurance schemes, which entitle them to full access to some 900 medicines on the country's essential drugs list. Many of these are patented. In addition, the government has committed to providing universal access to anti-retroviral drugs (ARVs) for HIV/AIDS victims since October 2003. Although public health spending now exceeds ten percent of the national budget, the country is still unable to fully achieve the goal of universal access to essential drugs due to the high prices of some patented medicines.

TRIPS Compliance

The 2001 Doha Declaration on the TRIPS Agreement and Public Health explicitly confirmed that the TRIPS Agreement "does not and should not prevent Members from taking measures to protect public health" and that it should promote access to medicines for all. There is no obligation in the TRIPS Agreement for a government to negotiate with the patent holder prior to issuing a compulsory licence for national emergencies, other circumstances of extreme urgency or public non-commercial use, although it must provide them 'adequate remuneration'. As remuneration, the Thai government will pay the patent holders a royalty fee of 0.5 percent of the total sale value of the generics.

No foreign government, including that of the United States, has claimed that the compulsory licenses infringe either Thai or international intellectual property laws.

New Price Reduction Strategy

After largely unsuccessful previous attempts to negotiate lower prices, the Thai government chose in the efavirenz, lopinavir/ritonavir and clopidogrel cases to suspend patent protection and then continue consultations with the affected companies since "it is only after the threat or the decision to use and implement compulsory licensing or government use of patents that the negotiation will be more successful and effective." The strategy appears to be working – at least in part – since Merck proposed in February a 'very favourable' new price, which the government is considering seriously. A 30-tablet bottle of brandname Stocrin would cost about US\$4 more than 30 generic efavirenz tablets imported from India.

The government also expresses disappointment that the strengthening of national patent laws to comply with the TRIPS Agreement has not led to more investment in drug research in Thailand or technology transfer from industry.

Selection Criteria

The National Health Security Board has established a special committee involving government departments and consumer groups to determine which drugs should be granted compulsory licenses and to set the royalty fees. The criteria upon which decisions will be made include, *inter alia*, whether the drug appears in the national essential medicines list; whether it is necessary to solve important public health problems, or; whether it is needed to deal with a national emergency or extreme urgency. In addition, the price of the original medicine must be too high for the government to be able to supply it to patients under national health insurance schemes.

Negligible Market Impact

According to the report, the compulsory licences are unlikely to affect the country's small market for patented drugs, as the majority of Thais cannot afford them and rely on medicines supplied by the government. The generic drugs will not be distributed to those who can afford private insurance, and such patients will continue to pay the higher price for patented products. The government argues that the generics in fact open a new market as those who receive them never had access to the patented drugs and would not be able to afford them now.

Benefits Already Clear

The Thai government justifies its intervention by stressing the threat to life perpetuated by lack of access to the most recent versions of ARVs, which are more effective and less more toxic than the older versions. The first batch of generic efavirenz imports from India has more than halved the price of the latest first-line ARV treatment, allowing 20,000 more people to be treated. Second-line ARV generics, such as lopinavir/ritonavir, are expected to cost about 80 percent less than the patented drugs now available. This would enable the government to support 8,000 more patients, who would not survive without second-line treatment. Just 2,000 AIDS victims are currently treated with second-line ARVs.