

## Thailand Could Seek WTO Solution On Compulsory Licensing, Generic Drugs

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SHANGHAI - Multinational drug companies and authorities across developed countries have censured Thailand for using compulsory licensing - a method of forcing pharmaceutical outfits holding patents on innovative medicines to allow other companies to turn out the product.

Now Thailand is expressing hope that the World Trade Organization can work out a solution on the production of low-cost generic drugs, Thai Trade Representative Kiat Sittheeamorn said in March.

Kiat said in Washington that Thailand recognizes patent rights, but added the country would like to see the U.S. engage with the WTO in order to come up with a multilateral regime that is good for all.

Thailand has envisioned a final goal of being able to provide affordable drugs for all Thai people while recognizing the rights of patent holders, according to Kiat.

Kiat said that the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) supports the use of flexibility in enforcing the agreement to improve access to essential medicines, in some cases through the use of compulsory licenses.

Section 51 of Thailand's Patent Act provides for implementing compulsory licenses.

Between November 2006 and January 2007, Thailand issued compulsory licenses for Merck's antiretroviral **Stocrin** (efavirenz), Abbott Laboratories' antiretroviral **Kaletra** (lopinavir/ritonavir), and Sanofi-Aventis' heart disease drug **Plavix** (clopidogrel).

In 2008, Thailand also announced compulsory licenses for three cancer drugs that include Novartis' breast cancer drug letrozole, Sanofi-Aventis' breast and lung cancer drug docetaxel and Roche's lung cancer drug erlotinib.

The move by Thailand's government to ignore patents on some cancer drugs introduced new legal disputes into the global pharmaceutical sector.

"Thailand's Patent Act addresses various types of voluntary and compulsory licenses. The Act limits the issuance of compulsory licenses to certain limited circumstances and provides the procedures which must be followed," said Siraprapha Rungpry, a Bangkok-based consultant in the intellectual property department of Tilleke & Gibbins International.

Rungpry told *PharmAsia News* that there is a dispute regarding the legitimacy or validity of compulsory licenses pursued by Thailand's Ministry of Public Health.

## **Thai Law Requires Government To Pay Patent Holder Royalty**

And while Thai law provides for the use of compulsory licenses, it also requires the government to pay a royalty on the forced use of a patented product to the patent holder after negotiations between the two sides.

"The Ministry and supporters of compulsory licenses have interpreted this to confer authority on the ministry to unilaterally issue compulsory licenses without prior consultation with the patent owners or the Department of Intellectual Property," said Rungpry.

"Thus, under this interpretation, patent owners would not have any opportunity to appeal the government's decision to issue the compulsory licenses or negotiate the terms and conditions thereof. This interpretation seems to bend section 51 of the Act beyond credible limits."

In January of this year, the U.S.-based manufacturing association PhRMA requested that Thailand be designated as a Priority Foreign Country - a means of censure - in the U.S. Trade Representative's 2010 Special 301 Report.

"PhRMA and its member companies operating in Thailand are concerned that the research-based innovative biopharmaceutical industry has been prevented from meaningfully participating in Thailand's efforts to reform the healthcare system," Mark Grayson, U.S.-based PhRMA spokesman said in an interview.

In 2009, Thailand announced that it intended to foster a better environment for intellectual property protection and increase dialogue between healthcare stakeholders and the Thai Government.

However, despite calls for a consultative dialogue mechanism between Thailand's healthcare stakeholders and the Thai government, no steps have yet been taken to create a system that allows PhRMA members to meaningfully contribute and voice policy concerns, according to Grayson.

### **Negotiation Process Ignored**

Rungpry explained that the Patent Act sets out the process for negotiations between the parties and the procedures that must be followed before a compulsory license can be issued by the Director-General of the Department of Intellectual Property. It also provides for an appeals procedure, which could allow patent owners an opportunity to subject the decision regarding compulsory licenses to judicial review.

At the same time, PhRMA is suggesting that the Thai government take steps to simplify the implementation of compulsory licenses.

PhRMA is encouraging Thailand to bring its regulations in line with international best practices to protect intellectual property rights.

For example, the group has proposed that Thailand implement new regulations that do not permit generics producers to rely directly or indirectly on the originators' data unless consent has been provided by the originator, or provide for the approval of

generic products during the designated period of exclusivity of the innovative product. The organization is also asking Thai officials to protect confidential information provided by the originator.

Critics say Thailand should introduce a better system to prevent regulatory approval of generic versions of drugs that are still covered by a valid patent.

Kiat told the American Chamber of Commerce in Thailand that the government was in talks with all sides and hoped for an eventual solution under the WTO.

Thailand is not alone in stirring up controversy over the use of compulsory licensing provisions to cut away at patent protections for innovative drugs.

Two years ago, China's national legislature amended the patent law to make it easier to force global pharmaceutical firms to license drugs to Chinese competitors in the event of a public health crisis.

Under the amended law, multinational drug companies that have patented products in China could be ordered by the government to allow local companies to turn out the drug to overcome an epidemic or other widespread health hazard, according to patent lawyers in Beijing and Shanghai ([PharmAsia News, Aug. 28, 2008](#)).

MNCs have voiced serious concerns about the breadth and ambiguity of China's compulsory license provisions ([PharmAsia News, Jan. 05, 2009](#)).

Yet some lawyers said that China aimed to provide safeguard measures for the quick production of medicines to fight a future public health crisis following the 2003 outbreak of the Severe Acute Respiratory Syndrome.

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