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# Celebrating 175 Years of Friendship between the United States and Thailand: 1833-2008

THIS EDITION'S FEATURES:



175 Anniversary of U.S.-Thai Relations 1833-2008

# Pharmaceutical Compulsory Licensing Update

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Approximately a year ago Thailand's Ministry of Public Health, led by the former Minister Dr. Mongkol na Songkla, decided to resort to compulsory licenses as a solution to improving access to medicines in Thailand. The Health Ministry issued the first set of compulsory licenses in late 2006 and early 2007 on Merck's antiretroviral Efavirenz (Stocrin®), Abbott Laboratories' antiretroviral Lopinavir/Ritonavir (Kaletra®), and Ssanofi-Aventis' heart disease drug Clopidogrel (Plavix®).

While the legitimacy of these compulsory licenses was questioned by the drug originators who own the patents, international legal experts and experts in the pharmaceutical field and other stakeholders, the more controversial and widely debated issue seemed to be whether the actions of the Thai Health Ministry would benefit Thai patients and help to improve the healthcare system and access to medicines in the long-run.

## INDUSTRY REACTIONS

Each of the patent owners whose drugs were subject to the compulsory licenses took a somewhat different approach to cope with the situation. Undoubtedly, each patent owner commenced dialogue and negotiations with the Ministry of Public Health (MOPH) directly in an attempt to resolve the issue amicably. Also, the pharmaceutical industry through Pharmaceutical Research & Manufacturers Association (PReMA) continued to make an effort to work with the Ministry to improve Thai patients' access to medicines and resolve compulsory licensing issues through collaboration and dialogue.

## JOINT COMMITTEE

PReMA's continuing efforts to create a linkage and collaboration between the industry and the MOPH, through which all parties can work together to improve the healthcare system in Thailand, has led to the establishment of the "Joint Committee between Representatives of the Ministry of Public Health and PReMA to Develop Sustainable Health Service System." The appointment of the Joint Committee was officially announced by the Ministry on December 17, 2007.

Although the Ministry expressly indicated that the Joint Committee will not have any role related to the decision making of any organization in announcing government use compulsory licenses, the establishment of the Joint Committee marked the first step towards concrete long-term cooperation between research-based pharmaceutical companies and the MOPH. The Ministry recognized that there are several challenges which affect health service system administration as a whole and that industry collaboration will help to facilitate the development of a sustainable national healthcare system.

In spite of the appointment of the Joint Committee and the various efforts taken by the drug originators to negotiate and cooperate with the Ministry to improve Thai patients' access to medicines, the Ministry has insisted upon implementation of its claim of right under the compulsory licenses to import generic products into Thailand through the Government Pharmaceutical Organization (GPO).

Earlier this year Dr. Mongkol na Songkla, the Public Health Minister from September 2006 to February 2008, signed a further announcement of compulsory licenses on three cancer drugs before the end of his term as the Health Minister. The new set of compulsory licenses include the breast cancer drug Letrozole produced by Novartis, the breast and lung cancer drug Docetaxel made by Sanofi-Aventis, and the lung cancer drug Erlotinib produced by Roche. The Health Ministry originally intended to announce a compulsory license on Novartis's leukemia drug Imatinib as well, but reversed that decision because Novartis agreed to provide the drug for free to patients under the universal healthcare scheme.

## LIMITATIONS ON COMPULSORY LICENSES

With regard to the debate about the validity of the compulsory licenses, it is essential to understand the process for issuing government use compulsory licenses as it is laid out in the Thai Patent Act. In addressing various types of voluntary and compulsory licenses in Sections 45-47 and 50-52, the Act limits issuance of compulsory licenses to certain limited circumstances and provides the procedures which must be followed.

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The various compulsory licenses pursued by the Ministry of Public Health

were based on Section 51 of the Patent Act, which addresses public non-commercial government use compulsory licenses. Section 51 permits government ministries and departments to seek compulsory licenses for certain purposes, such as to carry out service for the public consumption or defense of the country, to prevent or alleviate a severe shortage of food or medicine or other consumer goods, and for the sake of other public interests. Provided that the purposes for which a government department decides to seek a compulsory license meet the requirements of Section 51, a number of preconditions must be satisfied before a government department could actually obtain the compulsory license.

In order to understand the process for issuing compulsory licenses, a careful reading of Section 50 and 51 of the Patent Act is crucial. It is also important to keep in mind that, since Thailand is a member of the WTO, any interpretation of the Patent Act provisions must be consistent with the obligations under the WTO's Trade-Related Aspects of Intellectual Property Rights (TRIPs), although the TRIPs Agreement itself is not part of Thai law.

## SECTION 51 DISPUTE

Generally speaking, the dispute regarding the legitimacy or validity of the compulsory licenses pursued by the Ministry of Public Health stems from the first paragraph of Section 51, which appears to authorize government ministries and departments to exploit a patented invention by way of compulsory license, but the government department is required to pay a royalty after a period of negotiation with the patent owner. The Ministry of Public Health and supporters of compulsory licenses have interpreted this to confer the authority on the Ministry to unilaterally issue the compulsory licenses without prior consultation with the patent owners or the Department of Intellectual Property.

Thus, under this interpretation the 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 beyond credible limits.

Section 51 states in the second paragraph that "the ministry or bureau or department shall submit its offer setting forth the amount of royalty and conditions for the exploitation to the Director-General. The royalty rate shall be as agreed upon by the ministry or bureau or department and the patentee or his exclusive licensee, and the provisions of 50 shall apply mutatis mutandis."

Section 50 sets out the process for negotiations of the parties and the procedures which must be followed before a compulsory license could be issued by the Director-General of the Department of Intellectual Property to the applicant. Section 50 specifically states that "when the royalty, conditions for exploitation, and restrictions have been prescribed by the Director-General, he shall issue a licensing certificate to the applicant." In addition, Section 50 provides for an appeals procedure which would allow the patent owners an opportunity to subject the decision regarding compulsory licenses to judicial review. Thus, a careful reading of Section 51 and its reference to the procedures for issuance of compulsory licenses under Section 50 would seem to suggest that the Ministry of Public Health might not have taken the appropriate steps required by the Patent Act in seeking to impose compulsory licenses on various patented drugs.

Currently, the pressures from various interest groups and stakeholders remain strong both in Thailand and abroad. PReMA and its member research-based pharmaceutical companies continue to work with the Ministry of Public Health to improve Thai patients' access to medicines and to resolve the compulsory licensing issues amicably. In view of the new government, it is yet to be determined whether the existing compulsory license policy will be continued, or whether the new government will consider adopting a less drastic measure. ■

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