Compulsory Licensing Developments in Thailand

In a bid to improve public access to medicines, Thailand's Ministry of Public Health issued compulsory licences for a number of patented drugs without negotiating with the patent owners beforehand. In doing so, the Ministry may have exceeded the limits imposed by the Patent Act.

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A little more than a year ago, Thailand's Ministry of Public Health, acting on behalf of a post-coup military-appointed administration, decided to issue the first set of compulsory licences on three patented drugs. The three drugs were Merck's antiretroviral efavirenz (Stocrin®), Abbott Laboratories' antiretroviral lopinavir/ritonavir (Kaletra®) and sanofi-aventis' heart disease drug clopidogrel (Plavix®). The legitimacy of these compulsory licences was questioned by the drug originators who own the patents, international legal experts, as well as experts in the pharmaceutical field and other stakeholders. More importantly, it was widely debated whether the actions of the Ministry would benefit Thai patients and help to improve the healthcare system and access to medicines in the long run.

While each of the three companies took a somewhat different approach to deal with this issue, all of them commenced dialogue and negotiations with the Ministry directly in an attempt to resolve the issue amicably. The pharmaceutical industry, through the Pharmaceutical Research & Manufacturers Association (PReMA), also 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.

As a result of PReMA's continuing efforts to create a linkage and collaboration between the pharmaceutical industry and the Ministry, through which all parties can work together to improve the healthcare system in Thailand, PReMA and the Ministry agreed to set up 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 announced 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 so-called government use compulsory licences, the establishment of the Joint Committee marked the first step towards concrete long-term cooperation between research-based pharmaceutical companies and the Ministry. The Ministry recognized that there are several challenges impacting on the 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 various efforts of the patent owners to negotiate with the Ministry of Public Health, the Ministry insisted on implementing its claim of right under the compulsory licences to import generic products into Thailand through the Government Pharmaceutical Organization (GPO). Earlier this year, Dr. Mongkol na Songkla, the Public Health Minister between September 2006 and February 2008, signed a further announcement of compulsory licences on three cancer drugs before the end of his term. The new set of compulsory licences 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 Ministry originally intended to announce a compulsory licence 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.

The *Patent Act* addresses various types of voluntary and compulsory licences in sections 45 to 47, and sections 50 to 52. The Act limits the issuance of compulsory licences to certain limited circumstances and provides the procedures which must be followed. The various compulsory licences pursued by the Ministry of Public Health were based on section 51 of the Act, which addresses public non-commercial government use compulsory licences. Section 51 permits government ministries and departments to seek compulsory licences for the following purposes:

(i) to carry out any service for the public consumption or defence

of the country;

(ii) for the preservation or acquisition of natural resources and environment;

(iii) to prevent or alleviate a severe shortage of food or medicine or other consumer goods or foodstuffs; and

(iv) for the sake of other public interests.

Provided that the purposes for which a government department decides to seek a compulsory licence fall under one of the foregoing circumstances, a number of preconditions must be satisfied before a government department could actually obtain the compulsory licence.

In order to understand the process for issuing compulsory licences, a careful reading of sections 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 World Trade Organization (WTO), any interpretation of the Act's provisions must be consistent with the obligations under the WTO's *Agreement on Trade-Related Aspects of Intellectual Property Rights* (TRIPs), even though the TRIPs Agreement itself is not part of Thai law.

Generally speaking, the dispute regarding the legitimacy or validity of the compulsory licences 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 licence, but requires the government department to pay a royalty after a period of negotiation with the patent owner. The Ministry and supporters of compulsory licences have interpreted this to confer authority on the Ministry to unilaterally issue compulsory licences without prior consultation with the patent owners or the Department of Intellectual Property. Thus, under this interpretation, patent owners would not have any opportunity to appeal the government's decision to issue the compulsory licences or negotiate the terms and conditions thereof. This interpretation seems to bend section 51 of the Act beyond credible limits.

The second paragraph of section 51 states 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 licencee,

and the provisions of section 50 shall apply mutatis mutandis" (emphasis added).

Section 50 sets out the process for negotiations between the parties and the procedures which must be followed before a compulsory licence 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." Thus, a careful reading of section 51 and its reference to the procedures for issuing compulsory licences under section 50 would seem to suggest that, in seeking to impose compulsory licences on various patented drugs, the Ministry of Public Health has not taken the appropriate steps required by law. In addition, section 50 also provides for an appeals procedure, which would allow patent owners an opportunity to subject the decision regarding compulsory licences to judicial review.

Despite the ongoing debate as to the validity of the compulsory licences announced, and the various efforts made by the industry to cooperate with the Ministry, the former Public Health Minister Dr. Mongkol na Songkla seemed to believe that exercising compulsory licences on key patented drugs is the solution to improving access to medicines and upgrading the quality of Thailand's healthcare system. His decision to announce three more compulsory licences on cancer drugs before the end of his term was an indication of his position.

In view of the new government, it is yet to be seen whether the compulsory licence policy will be continued, or will be reconsidered and perhaps replaced by a less drastic measure.

About the authors

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