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DEVELOPMENTS IN COMPULSORY LICENSING

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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 licenses 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 licenses 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 of Public Health directly in attempting to resolve the issue amicably.

In spite of the various efforts taken by the patent owners to negotiate and work with the Health Ministry to improve Thai patients' access to medicines, the Ministry 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 between September 2006 and 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.

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 license for the following purposes: (1) to carry out any service for the public consumption or defense of the country; (2) for the preservation or acquisition of natural resources and environment; (3) to prevent or alleviate a severe shortage of food or medicine or other consumer goods or foodstuffs; and (4) for the sake of other public interests. Provided that the purposes for which a government department decides to seek a compulsory license fall under one of the foregoing circumstances, 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 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 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. 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 Section 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*

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issue a licensing certificate to the applicant." 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 has not taken the appropriate steps required by law in seeking to impose compulsory licenses on various patented drugs. In addition, it should be noted that Section 50 also provides for an appeals procedure, which would allow the patent owners an opportunity to subject the decision regarding compulsory licenses to judicial review.

It has yet to be determined whether the new government will maintain the existing compulsory license policy, or whether the policy will be reconsidered and perhaps replaced by a less drastic measure. ♦