



DECREE OF DEPARTMENT OF DISEASE CONTROL, MINISTRY OF PUBLIC HEALTH,  
REGARDING

EXPLOITATION OF PATENT ON DRUGS & MEDICAL SUPPLIES BY THE GOVERNMENT  
ON COMBINATION DRUG BETWEEN LOPINAVIR & RITONAVIR

---

Article 51 of the Thai Patent Act B.E. 2522 (as amended by the Thai Patent Act no.2 B.E. 2535 and no.3 B.E. 2542) states that, for the public use, ministry or department may exploit any patent without further negotiation with the patent holder. This implication makes clear that, for non-commercial use, especially in public affairs of the government such as public health services, government is well within its rights.

The situation of HIV spreading is the key problem of Thai public health. More than 1 million Thais have been infected with HIV, among this, more than 500,000 people are still alive. These infected individuals will eventually need long-term uses of antiretroviral drugs to maintain their productive lives. The Thai Government has launched a policy of universal access to anti-retrovirals since 1st October 2003, and has a budget specifically allocated for them. However, it is still difficult to get accessed to some effective and safer anti-retrovirals. The high price of these patented anti-retrovirals have hindered their accessibility under the universal access policy because of patent protection by law, then there's no competition. The government cannot allocate enough budget. However, budget for health services in the national health security system allocated for HIV /AIDS patients in the fiscal year 2007 (B.E. 2550) is only 3,855.6 million baht for the target group of 108,000 patients. Some of this group have resistance to the first line ARVs and have to move to the second line.

Lopinavir + Ritonavir under the tradename Kaletra is a highly effective and safe anti-retroviral. It is also placed in the Thailand's National List of second line Anti-retrovirals. Because it's protected by patent, no one can produce or import to share the market. So, its price is much higher than generic products in some other country. With this higher price, the budget allocated from the Thai Government can only cover some patients with it, whereas the rest has to face with fatal opportunistic infections. If this ARVs formula could be produced or imported, the lower price would help more accessible.

Under the Doha Declaration on TRIPs and Public Health, it notifies that each member state has the right to protect public health in particular to promote access for medicines for all, by granting compulsory licenses in cases which constitute a national emergency or other circumstances of extreme urgency and of public health crisis, including those relating to HIV/AIDS, tuberculosis, malaria or other epidemics. While Section 51 of Thailand's Patent Act defines the right of "any ministry, or department of the Government," "by themselves or through others," to exercise the rights in any patent "for public consumption", without commercial use as mentioned above.

By the virtue of provisions of Article 51 of the Thai Patent Act B.E. 2522 (as amended by the Thai Patent Act no.2 B.E. 2535 and no.3 B.E. 2542), the Department of Disease Control, Ministry of Public Health, thus use the patent right of a medicine called Kaletra®(or Lopinavir+Ritonavir as a generic name) and endorse the Government Pharmaceutical Organization of Thailand to exercise the rights contain within Para 1 of Article 36 of the Thai Patent Act B.E. 2522 (as amended by the Thai Patent Act no.2 B.E. 2535 and no.3 B.E. 2542) under these conditions:-

- (1) The use of the above patent rights are effective from today to the 31st January 2012.
- (2) The use of the above patent rights will be limited to the provision of Efavirenz to not more than 50,000 patients per year, for those covered under the National Health Security System Act B.E. 2545, Social Security Act B.E. 2533, and the Civil Servants and government

employees medical benefits scheme..  
(3) A royalty fee of 0.5 percent of the Government Pharmaceutical Organization's total sale value of the imported or locally produced Lopinavir+Ritonavir will be paid to the patent holder.

The Department of Disease Control, Ministry of Public Health will notify the patent owner and the Department of Intellectual Property, Ministry of Commerce immediately.

This decree is announced to the public.

Issue on 29 th January 2007.

(Mr.Thawach Suntrajarn)  
Director General of The Department of Disease Control