

Dear Director General, Department of Intellectual Property,

Thai Network of People Living with HIV/AIDS (TNP+) and non-government organizations working on AIDS, access to treatment, and public health have a grave concern when we acknowledge that Gilead Sciences, Inc. has applied for patents on the fixed-dose combination AVR tenofovir + emtricitabine (TDF+FTC) in Thailand with claims on dosage/dose, formulation, and combinations. These ARV's patent applications should not be awarded as they do not meet the patentability criteria, in accordance with the Thai Patent Act and the pharmaceutical science's principles. Due to the problematic patent database and the mere 90-day pre-grant opposition period, it is a barrier preventing others to oppose in time. The country's HIV & AIDS treatment will be severely affected and the national goal of the HIV treatment scale-up is impossible if the Department of Intellectual Property (DIP) agrees to approve patent applications on TDF+FTC.

In Thailand, the ARVs with the combination of TDF are effective HIV-treatment regimens and adopted to be alternative first-line regimens to treat HIV & AIDS and a HIV co-infection disease, Hepatitis B. The medicine has been included in the National Essential Drug List (NEDL) and in the national HIV treatment guideline since 2010, and later on it has also been in the NEDL for Hepatitis B treatment since March 2012. Therefore, PLHIVs who need this ARV - as they cannot tolerate adverse side-effects from the use of the other ARVs, have HIV co-infection Hepatitis B, or have some limitations to other ARV regimens, will be able to access effective treatment and regain their better quality of lives.

But, as we can search for information on the DIP's online database (as attached), it is found that there are 3 patent applications related to TDF - application number 0601002699, 0601002700, and 0401000086. Two applications were filed on June 8, 2006 and the other on January 13, 2004, with 3 types of claims including 1) dosage/dose, 2) formulation, and 3) combinations.

According to the international patentability standard and the Thai Patent Act (section 5), there are 3 essential criteria to consider, which are 1) novelty, 2) inventive step, and 3) capability of industrial application. By these criteria, the PLHIV network and NGOs consider the fixed-dose combination TDF+FTC is not entitled to get patents with the 20-year protection. This is because TDF is not a newly invented drug and it has been existed for a long time. And, its combination requires no high technology to prove significant inventive steps. So, the DIP should not approve all the 3 patent applications filed by Gilead Sciences, Inc.

TNP+ and the NGOs working on AIDS, access to treatment, and public health had several meetings with relevant government agencies, including DIP, and repeatedly expressed our concerns on the patent application system, especially for pharmaceutical products, that it is a problematic system. As a result, a large number of ever-greening patents have been granted. Referring to a research on pharmaceutical patents in the last 10 years (2000 – 2010), which is conducted by a group of Thai pharmacist academia, it shows that over 90% of those patents are ever-greening patents, as they are not complied with the 3 essential patentability criteria, in accordance with the Patent Law, and the pharmaceutical science's principles. The research was presented in the meetings between the DIP and stakeholders, at least 2 times. In the final meeting, it was agreed that a manual of patentability for pharmaceutical products should be developed so that the DIP's patent officers will be able to amine patent applications stringently in order to safeguard people's health benefits, rather than in favor of the private sector's economic benefits.

Nevertheless, it is also found that the search for patent status and patent applications is problematic; unease to search, not updated information, incorrect information, and lack of clarity in required information stated in patent applications, etc. Such a practice, it becomes a loophole that the multinational pharmaceutical industry can take advantage and block and/or delay the local generic-drug industry's competition, including the state-enterprise Government Pharmaceutical Organization (GPO). When it is difficult to have correct and complete information, the generic-drug manufacturers cannot be aware of the patent expiry and the patent applications' details. Then, they cannot prepare to produce and market their generic products to compete at lower prices on a timely basis.

Last but not least, the pre-grant opposition period is limited to 90 days only - it is consider too short, and it is hard for the public to access the patent application publication. Thus, it becomes a barrier for people or organizations who want to oppose. In this case, TNP+ and NGOs could not file opposition in time (information of the application publication dates, as attached).

Therefore, TNP+ and NGOs working on AIDS, access to treatment, and public health would like to urge the DIP to take the following actions:

- DIP should not approve all the three patent applications.
- DIP must accelerate the development of the patent examination manual for pharmaceutical products by taking civil society's concerns and the ever-greening patent research into account and with the recognition of the public's interest before the particular business groups' benefits.
- The working group to develop the manual should be comprised of capable human resources with sound knowledge both in patent and pharmacy and without any conflict of interest.
- DIP must urgently improve its patent database system to be convenient to search and provide correct, complete and updated information.

Sincerely yours,

Thai Network of People Living with HIV/AIDS AIDS
Access Foundation
Alternative Agriculture Network
Friends of Kidney-Failure Patients Club
Cancer Patient Network
Foundation for Consumers
The Rural Pharmacist Foundation
Foundation for AIDS Rights
Thai NGO Coalition on AIDS Drug Study Group
Biodiversity and Community Right Action Thailand, (Biothai)
Thai Holistic Health Foundation
Ecological Alert and Recovery
Thailand FTA Watch