2 Impacts of Intellectual Property Rights Negotiations on Thailand's Drug System

The Free Trade Agreement (FTA) negotiation framework between Thailand and the European Union, which includes negotiation on drug patents, was recently approved by the Thai Parliament on January 29th 2013. The FTA has solid support from capitalists but is at the same time strongly opposed by government agencies and civil society, both of whom are concerned that the impact of the FTA on the country's access to drugs and general public health have not been a primary part of the considerations. Opponents are concerned that Thailand would be at disadvantage if the negotiation is conducted within the framework of intellectual property rights (IPR) as drug patenting will then allow a monopoly with wider and longer impacts. As a result, Thailand may become more dependent on imported drugs with higher prices, the local drug industry may be weakened and the public's access to drugs may be impeded.

Structural problems facing Thailand's drug system

Thailand boasts an internationally–acclaimed health security system under which the population has universal access and people can afford treatments even for diseases with high treatment costs. Although the Thai health system has become a model for neighbouring and other countries around the world[1], it is not without its own problems, especially when it comes to inequality. While the budget for 4.9 million civil servants is as high as 62.195 billion baht per year, the national health security system gets a budget of only 120.846 billion baht per year to cover 47.7 million people. As a result, the civil servant healthcare system costs four times that of the national system.[2]

Drug Patenting and FTA Negotiations

A patent is a legal document issued for the protection of an invention. The patent holder has, for a fixed period of time, exclusive rights to produce, use, sell, possess to sell, solicit to sell or import the protected invention. Patents create incentives for new inventions, encourage foreign investments and leads to transferal of technology from the inventor to the public through the disclosure of the details of the invention. However, the exclusive rights of patent holders may make the products difficult or expensive to access, especially products that are essential to life, such as medicine.

In general, developing countries have a lower capacity to patent new inventions and less purchasing power to access patented products. As a result, such countries usually provide less stringent patent protections. Developed countries however often use multilateral negotiations like the WTO forum to force developing countries to tighten patent protection in line with the Trade–Related Aspect of Intellectual Property Rights (TRIPS), which specified minimum levels of protection for seven types of intellectual properties including: copyrights and related rights; trademarks; geographical indications; industrial designs; patents; integrated circuit layout designs; and undisclosed or confidential information.

TRIPS requires all party countries to grant patents to inventions in all technological fields including pharmaceuticals. This is one reason why challenges relating to access to drugs are on the rise in developing countries as multinational drug companies or big pharmaceutical companies gain monopolies through drug patenting. As a result, TRIPS has specific provisions on drugs such as the protection of undisclosed information and the flexibility allowed in adopting certain measures for public health purposes including; the exception on drug registration as necessary (to facilitate immediate market entry of generic drugs after the patent of the original drug expires); parallel import (to allow imports from another country of cheaper versions of patented drugs without authorisation of the patent–holder in the country); and compulsory licensing (CL, which a government or authorised entity can use as necessary such as in the case of emergency for non–commercial/public purposes.). These measures encourage competition between the original drugs and generic versions to increase access of the population to the concerned drugs.

Source: 1. Poonsin Wongkolthut (Ed.). 2010. *TDRI Special Report: Developing Thailand's Drug Patent System and Preparedness for the Impacts from FTA Negotiation on Drug Patenting, 18*(83, June): 5–7.
2. Suchart Chongprasert. 2007. *Ten Q&As about TRIPS*. Nonthaburi: Generic Drug Industry and Intellectual Property Rights Group, Drug Control Department, Food and Drug Administration, Ministry of Public Health.

In addition, national healthcare expenses have also been increasing at an annual rate of 9%, accounting for 4% of GDP.[3] The proportion of healthcare–related expenses (medicine and treatments) in 2011 accounted for 6.5% of total household expenses.[4] In 2010, drug expenses accounted for 35% of all healthcare–related expenses.[5]

Dr. Samrit Srithamrongsawat, Director of the Health Insurance Systems Research Office, described the situation as follows: "Service providers order as much supply as they can. Patients don't need to pay anything out of their own pockets. Hospitals also earn the differences in drug prices. But those who benefit most are pharmaceutical companies, especially those importing drugs. In 2008, Thailand paid 270 billion baht in drug expenses. 65% of this was for imported drugs. This gave the drug companies astronomical profits because there is no price ceiling."[6]

In fact, there are many structural problems in Thailand's drug system waiting to be solved, including: inappropriate drug uses; false advertisements of drugs and food products; unethical marketing by drug companies; an out–of–date Drugs Act that is ineffective against old and new problems[7]; as well as an inefficient patent database and IP validation system that cannot cope with the problem of evergreening patent.[8]

While these challenges have not been solved, Thailand's public health and drug systems must now face a new and even bigger challenge, that is, FTA negotiations on drug–related intellectual property issues.

TRIPS Plus

TRIPS Plus is an obligation to protect patents beyond TRIPS requirements. Its most important features include:

1. Data exclusivity is a protection of exclusive rights to data from clinical trials that prevents governments from using the data to register a generic version, even when the drug is not patented in the country or the patent has already expired or been revoked.

2. Extension of patents beyond 20 years and increased level of protection, such as allowing patented drug to be registered for new patents when used or manufactured in a different way. This enables the drug to dominate the market even longer.

3. Increased restriction on the use of public health measures such as compulsory licensing, parallel import and drug registration, to limit the population's access to the drug.

In addition, there are requirements not to object to patent application before issuing the patent, the use of international arbitration which allows a multinational pharmaceutical company to sue the government if it claims to have suffered from the country's public health policies and the use of border control measures which require customs officials to seize generic drugs being imported or transported if suspected of violating IP.

Source: Kannikar Kittivejjakul. 2011. Thai people's access to drugs: Lessons from the past for the future. in Yuphadee Sirisinsuk (Ed.). *Situation Report on Drug System 2011*. Bangkok: Drug Surveillance and Drug System Development Group, Faculty of Pharmacology, Chulalongkorn University, p. 20.

Drugs and trade negotiations

Economically powerful countries often employ measures to force developing countries to tighten their patent laws to levels higher than the minimum TRIPS requirements, especially in exchange for trade privileges in bilateral and multilateral negotiations. Thailand revised patent laws in 1992 in accordance with TRIPS, expanding patent protection to include drugs and extending the length of protection from 15 to 20 years.[9]

According to the report of Thailand's Food and Drug Administration (FDA), in 1990 before the amendment of the Patent Act (Second Edition) 1992, the value of imported drugs accounted for 32% of the total value of all drugs. However, after this amendment the value and proportion of imported patented drugs began to rise, reaching 69% of the total value in 2010, while the proportion of domestically manufactured drugs fell to just 31%.[10]

This trend is likely to continue. It is estimated that by the end of 2012 the proportion of patented imported drugs will top 75% while domestically manufactured drugs will account for only 25% of total value.[11]

If this situation continues, Thai people will have increasing difficulties in accessing new essential drugs and the country will have to shoulder a heavy economic burden.

As a result, access to drugs has become a hot issue relating to intellectual property (IP) negotiations. An example is the US–Thai FTA negotiation between 2004 and 2006 when academics called the US's demand as "more terrible than expected."[12] Several agencies including the FDA, the Department of Intellectual Property, the Department of Trade Negotiations, the Ministry of Commerce, the National Human Rights Commission, the National Economic and Social Advisory Council and the National Health Commission Office agreed that although the FTA could yield economic benefits, ***Thailand should not yield to demands that go beyond TRIPS***, especially in the extension of patent protection period, drug data exclusivity and border control measures that patent holders may abuse in order to stunt competition from domestic drug manufacturers.[13]

This position was in line with opinions and recommendations of several UN organisations such as the World Health Organisation (WHO), the United Nations Development Program (UNDP) and the United Nations AIDS Programme (UNAIDS). Moreover, the United Nations Conference of Trade and Development (UNCTAD) issued a briefing paper advising developing countries against yielding to IPR demands beyond TRIPS, especially regarding drug data exclusivity issues, and to retain as much flexibility in relation to TRIP in national laws as possible in order to use such laws as a tool to solve public health problems.[14]

However, the issue became heated again in the second half of 2012 when the EU and the US sent signals that they will cut the privileges of many Thai products under the Generalised System of Preferences (GSP). Thai exporters of prawns stated that, as a result, frozen prawns from Thailand would be slapped with a 12% tariff (up from 4%) and seasoned prawns 20% (up from 7%) such that they requested the government to open FTA negotiation with the EU. As these new trade negotiations may take up to two years, exporters suggested that the Government offer certain concession in exchange for the EU's delay of the measure or otherwise Thailand's prawn exports would lose out to rivals with GSP privileges such as India, Vietnam and Indonesia.[15]

On the other hand, civil society and public health agencies were of the opinion that the increase in GDP that an EU–Thai FTA may boost was not worth the possible negative impacts on the healthcare system. For example, drug data exclusivity, one of the EU's strongest demands,

would result in an increase of 81.356 billion baht in Thailand's annual drug expenses, affecting the Thai population's access to drugs, quality of life and health as well as the development of Thailand's pharmaceutical industry.[16]

Impact of the EU–Thai FTA Negotiation Framework

Many sectors of Thai society have voiced concerns about the EU–Thai FTA negotiation. The National Economic and Social Advisory Council submitted recommendations to the Cabinet on the issue whilst a group of 84 academics in the fields of pharmacology, medicine, public health, social development, consumer protections and human rights protection sent a letter to Prime Minister Yingluck Shinawatra. The Food and Drug Administration also submitted relevant information to the House of Representatives' Public Health Commission and the Monitoring Committee on Impacts of FTAs on Health and Health Policies under the National Health Commission submitted a letter to Deputy Prime Minister Kittirat Na Ranong and Plodprasop Suraswadi, Chairman of the National Drug System Development Committee. This letter was also submitted to other related agencies.

The Ministry of Commerce then tabled the EU–Thai FTA negotiation framework for consideration of the Cabinet, resulting in a Cabinet resolution on December 4th 2012. A public hearing was then held on January 23rd 2013 at the Office of the Permanent Secretary of the Ministry of Commerce. However, no high–ranking executives from the ministry were present.[17]

The Parliament elevated consideration of the FTA framework as an urgent agenda topic and the Framework was then approved on January 29th 2013.[18] The framework is said to be in line with WTO agreements such that it follows rules set down in TRIPS and not TRIPS plus.

Soon, actual negotiations on the EU–Thai FTA and TPP agreement will begin with the hope that both trade agreements will come into force in the beginning of 2015 in order to extend GSP privileges demanded by the business sector.[19] However, all eyes will remain fixed on IPR negotiations in relation to drugs and Thailand's overall health system given fears that capitalists and big pharmaceutical companies will exploit this opportunity to renegotiate terms to their benefit

A common position from many parts of Thai society remains the same, that is a rejection of any demands beyond TRIPS to prevent monopolisation of drugs for longer time and with higher prices. It is clear that increased patent protection does not lead to new drug development or transferal of pharmaceutical technologies to Thailand, as previously claimed.[20] The only impact of patent protection are increased dependency on imported drugs, higher health–related expenses and more difficulties in accessing drugs.