

Impact of Thailand-US Free Trade Agreement on Thai Drug System

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Objective:

To analyze the impact of Thailand-US Free Trade Agreement on the Thai drug system.

Methods:

The unobtrusive methods were used for content analysis.

Results and Discussions:

There is no Thailand-US negotiation text was released, so it was assumed to be based on the fact sheet released from the White House in October, 2002¹ stated the roadmap to FTAs between the U.S. and individual ASEAN countries, the USTR notified Congress of intent to initiate FTA negotiations with Thailand on February 12, 2004², and all the agreements that the US dealt with other countries, such as Singapore, Chili, Morocco, and Jordan. The main issues related to the intellectual property rights (IPRs) on pharmaceuticals are: 1) the patent term can be extended to compensate for up-front administrative or regulatory delays in granting the original patent; 2) provides the market exclusivity via data exclusivity for a period of 5 years on test data and trade secrets submitted to a government for drug registration process; 3) ensures that government marketing-approval agencies will not grant approval to patent violating products; 4) provides protection for patents covering biotech plants and animals; and 5) protects against imports of pharmaceutical products without patent-holder's consent by allowing lawsuits when contracts are breached.

The regulatory delay in granting patent was happened according to the patent applicants³. Any how the patent term in Thai Patent Act is 20 years from filing date, therefore the delay in the process of patent granting do not affect the right of patentee. There is no obligation in the drug registration to wait for the granting of patent and the patentee has the full right for the invention even though the application is still in the granting process. In contrary, there is no regulation in the Thai drug registration process to enforce the patentee to elaborate the patent status of registered drug. In consequence, it delays the introduction of generic product into the market about 5 years after the patent expiry date of those drugs. The longer market monopoly, without any price regulation mechanism, means the longer existing of the high price drug in the market.

The request of data exclusivity on the test data came from the statement of the PhRMA in the report to USTR⁴ that Article 39.3 requires the introduction of "data exclusivity", even though Article 39.3 obliges WTO member countries to protect undisclosed test data of a new chemical entity made for registration purposes against disclosure and unfair commercial use. Clearly, no parts of Article 39.3, create a "market exclusivity" in information. Consequently, Article 39.3 cannot prevent a regulatory authority from using/relying on the data of a registered product in order to assess and register other "similar" products so long as this information is not disclosed. The PhRMA proposed interpretation is therefore beyond TRIPs and would, if applied, have a major negative impact on access to medicines and the development of local generic pharmaceutical companies.

¹ <http://www.whitehouse.gov/news/releases/2002/10/print/20021026-7.html>

² <http://www.ustr.gov>

³ Jiraporn Limpananont et al, "The database of drug patent in Thailand", Final report submitted to Thai Food and Drug Administration, July 2004 (69 pages).

⁴ PhRMA "Special 301" Submission Priority Watch List Countries