

Thesis Title : Impact of exclusive right on Data Exclusivity in Thai Pharmaceutical
Registration Legal System

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ABSTRACT

TRIPs Agreement article 39.3 appointed that test data used in drug registration must be protected against unfair commercial use. Thailand drug registration system is one cause of unfair commercial use because it allows generic manufacturers to refer the original manufacturer's data in their registration without permission. More over, the originator did not receive any compensation from data referencing. So generic drug registration cost is lower than original drug registration cost, which leads to unfair competition in pharmaceutical business and not comply with Thai Constitution section 50 and 87. Data Exclusivity Law would solve this problem because it provide that, for a specified period the regulatory agency must not, without the originator's consent, access the originator's data when considering an application from a generic competitor seeking approval to sell an equivalent product. The originators will have a time frame, as a compensation, to sell products before generic manufacturers. Data Exclusivity Law would not affect those who do not use original manufacturer's data in their registration, and would not much affect local pharmaceutical production and prices.

During the meeting on Free Trade Agreement between Thailand and the United States of America, Data Exclusivity Law is expected to be proposed as an negotiate issue for Thailand drug registration system. Thailand should to strict to the North America Free Trade Agreement because it conforms to Trade Agreement on Intellectual Property article 39.3 which is clear and fair.