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DATA PROTECTION UNDER TRADE SECRETS LAW

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In 2002, Thailand adopted the Trade Secrets Act which contains a provision intended to safeguard the confidentiality of marketing approval data submitted to the Food and Drug Administration (FDA). Nevertheless, the scope of the protection afforded by the Act would remain uncertain until ministerial regulations were adopted which would enable its implementation. This means in spite of the express legal protection for such data, drug originators cannot wholly rely on the government authority to protect confidential data and information submitted against unauthorized disclosure and/or unfair commercial use.

Generally speaking, the Trade Secrets Act 2002 (B.E. 2545) creates a legal framework for the protection of trade secrets and other confidential information, rendering the unauthorized use and disclosure of such information an actionable and even criminal offense. With respect to data or information submitted to the FDA by a drug originator in order to obtain an approval to market a new drug, the Act recognizes that such data or information, either in whole or in part, may amount to a trade secret in the form of testing result or other information regarding its preparation, discovery, or creation. In this case, the owner would have the right to request the FDA to maintain the confidentiality of the data submitted. Upon such request, the FDA would have "*the duties to maintain the trade secrets from being disclosed, deprived of or used in unfair trading activities, in accordance with the regulations prescribed by the Minister.*"

Since the Patent Act clearly confers generic drug manufacturers with the ability to engage in

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various preparatory activities with a view to seeking regulatory approval before a patent for a particular protected drug has expired (i.e. Bolar provision), generic manufacturers could submit applications for regulatory approval before the expiration of the patent. As a result, the extent to which the drug originator's data submitted to the FDA is protected, or in other words, the extent to which a generic drug manufacturer may rely on previously filed data which underpins the efficacy and safety of the drug to support the application for marketing approval for a generic becomes a critical issue.

Thus far, the FDA has treated an originator's data on file as forming part of known scientific knowledge and does not require a generic applicant to prove safety and efficacy of a drug compound. Follow-on applicants are usually required to conduct the less onerous bioequivalence and/or stability testing to demonstrate that the follow-on genetic drug compound is either bioequivalent or has the same bioavailability. Similarly, the generic manufacturer does not need to conduct research on ingredients and dosage forms that have already been approved for safety and effectiveness. Questions arise about whether the foregoing practice violates the mandate of the Trade Secrets Act and/or TRIPS obligations with regard to data protection. While the FDA acknowledges it must refrain from disclosing the data submitted by drug originators to third parties, generic manufacturers which are direct competitors of the drug originators clearly obtain a commercial benefit from the originator's confidential data on file.

Although TRIPS mandates that member countries must provide protection against unfair commercial use of marketing approval data, countries do reserve considerable discretion to define "unfair" in the context of their national laws. Since the Trade Secrets Act does not specifically address this, the ministerial regulations adopted under the Act should have provided guidance as to whether the FDA's reliance on the data submitted by the drug originator in order to assess a subsequent application constitutes "unfair commercial use" although the originator's data is not actually disclosed to the generic applicant.

The ministerial regulation regarding data protection has been passed and was published in the official gazette on September 6, 2007. Before the regulation was adopted, it had widely been anticipated that the regulation would clearly establish the breadth of data protection and/or data exclusivity under the Trade Secrets Act. When the ministerial regulation was announced, it was viewed by the pharmaceutical industry and interested parties as somewhat of a disappointment. The regulation fails to provide a clear solution to this highly controversial issue, and to the disappointment of drug originators, it hardly protects data owners against unfair commercial use, as prescribed by the Trade Secrets Act in compliance with TRIPS obligations.

While the real issue with regard to data protection is the extent to which the originator's sensitive and confidential data on file at the FDA could be referred to or relied on by generic manufacturers to support their applications, the ministerial regulation evidently sidesteps this issue and does not define the limits or boundaries of data protection in a meaningful way. Whereas the regulation purportedly establishes a standard for protection of data submitted to the FDA, the relevant sections (e.g., Sections 16-18), merely address physical security of the documents submitted and simply prevent unauthorized (actual) disclosure. For instance, Section 16 of the regulation provides that in case of application for drug registration, the data submitted must be stored in a securely locked cabinet, etc.; Section 18(2) merely states that government officials have the responsibility to protect/keep the trade secret information in a safe place.

Thus, the ministerial regulation adopted does not really provide additional guidance for the implementation and enforcement of the Trade Secrets Act in respect of data protection. Presumably, in light of the current view of the FDA which favors the narrow interpretation of its obligation under the Act, the regulation would allow generics producers to continue to exploit drug originators' confidential data on file, even though this practice may be regarded as an unfair commercial use under the Trade Secrets Act because it unfairly confers commercial benefits on generic manufacturers. Nevertheless, while it could be argued that the (indirect) use of data by the FDA to approve a subsequent generic application would essentially confer commercial benefit on a third party and therefore constitutes "unfair commercial use," many simply believe that the use by a state agency in granting marketing approval to a follow-on applicant based on the second product's similarity to the originator's previously approved product cannot constitute an unfair commercial use of data because the FDA itself is not a commercial entity. Unfortunately, the ministerial regulation recently adopted does not provide much guidance on this particularly controversial issue. ♦