Drug Originator's Liability for Damage Caused by Use of Generics

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After several years of consideration, Thailand has recently adopted a product liability law that holds business operators strictly liable for unsafe or defective products which cause harm to consumers. Product quality and liability concerns reached a high point in the summer of 2007 during the middle of the China scare, when a wide variety of shoddy products were recalled in the United States, such as faulty blade guards on electric saws that injure users, baby carriers and baby swings that injure children, tainted pet foods, cosmetics containing various toxins, and toys containing high levels of lead paints. As Thailand begins to embrace the product liability concept with very few precedents in this area, the possible extent of liability may be estimated by observing cases in the United States, where product liability law is well established.

Pharmaceutical companies are often targets of product liability claims, and sometimes their liability goes further than anyone would have expected. The U.S. Hatch-Waxman Act states that a generic manufacturer is not required to submit evidence on drug safety and efficacy. The generic manufacturer merely needs to certify that its product is bioequivalent with the brand-name drug and that the labeling and warnings information shall mirror those of the approved brand-name drug. A question arose in 1994 as to whether a pioneer manufacturer could be held liable for damage caused by the generic equivalent, since the generic was the bioequivalent of the brand-name drug and had the same labels and warnings. The Fourth Circuit Court stated that the pioneer manufacturer could not be held liable for the "injuries caused by other manufacturers' products over whose production the name brand manufacturer has no control." This case was followed by the U.S. courts until last November.

In a decision rendered in November 2008 by the California Court of Appeal for the First Appellate District, a pioneer pharmaceutical company was held liable for injury to a patient who took the generic version of its brand-name drug. The pioneer's drug was no longer being sold on the market. After taking the drug for almost four years, the plaintiff claimed that she developed significant complications.

According to the relevant U.S. law, only the manufacturer of the product injuring a patient can be sued. The plaintiff initially raised an inadequate warning claim on the product labeling, but the plaintiff's doctor did not actually remember reading the label provided by the generic manufacturer. Thus, no product liability claim could be raised against the generic manufacturer, nor could such claim be brought against the originator company, which did not manufacture the litigious drug. The Court authorized the plaintiff to reformulate her action by accusing the originator company of fraud, fraud by concealment, and negligent misrepresentation. In his testimony, the doctor testified that he may have relied on the label of the original drug, which he probably became aware of during his residency, implying an extension of duty of care owed by the originator company.

The Court of Appeal in California recognized the so-called "innovator theory" and stated that the originator company had the duty to warn patients whose doctors are relying on their

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labeling prescription, regardless of whether the patients are taking the brand-name product or its generic. The Supreme Court of California declined to hear the case.

Since this decision, rulings in February and March 2009 by U.S. District Courts in Texas, Oklahoma, and Iowa have rejected the claims of patients who were prescribed generic drugs against the brand-name manufacturers for allegedly failing to warn doctors about the risks associated with the generic products. Thus, this controversial California case may not be followed by other courts, but still must be taken into consideration by pharmaceutical companies.

If similar claims against drug originators were to be raised in Thailand by a patient who sustained injury from taking a generic version of a brand-name drug, under strict interpretation of applicable Thai laws, the chance of success for such claims would appear rather slim. Owing to the fact that the injured patient is using the generic drug, as opposed to the original drug, the patient would not have a cause of action against the originator company for product liability. In order to claim damages under the Thai Product Liability Act, the injury sustained must be caused by the product of that particular company. The Act specifically states in Section 6 that in order for the business operator to be held liable, the injured party "must prove that the injured party has sustained an injury from the product of the business operator."

In Thailand, if the product that caused damage to the patient was not manufactured by the originator company, the originator company should not be held liable as it did not make or sell the product to the injured patient. The same analysis would be equally applicable in the case where a patient used a counterfeit drug and consequently sustained injury because of it. The originator company cannot be held liable for such damage since it did not make or sell such counterfeit product to the patient. Similarly, where the patient developed complications due to taking a generic version of a brand-name drug, only the generic manufacturer who makes and/or sells the unsafe or defective product would likely be subject to liability under Thai product liability law.

Aside from the Product Liability Act, the Consumer Protection Act also prescribes general standards for product labels. Unlike the Product Liability Act, however, the Consumer Protection Act does not provide direct standing for consumers to bring an action in court. Complaints have to be submitted to the Consumer Protection Board for review and investigation. Additionally, the Drug Act requires drug companies to submit product labels to the Thai Food and Drug Administration (FDA) for review and approval. Subsequent to approval of the labels, the FDA is also responsible for monitoring to ensure that the information printed on the product labels and inserts is consistent with the text approved by the FDA.

Thus, if an injured patient were to raise a claim that the originator's product label does not provide sufficient information and/or warning with regard to side effects or complications which may result from taking the drug, such claim would have to be referred to the relevant government authority to review and determine whether such claim has any merits, rather than being able to bring an action in court directly. Otherwise, as more or less the last resort, the injured patient may try to bring a general tort claim against the drug originator. Given that the drug originator has not breached its duty under the law, the chance of success for such tort claim would be rather slim, as it would be difficult to establish causation in this particular scenario. ❖