

Generic companies free from prosecution

WASHINGTON, USA: Manufacturers of generic drugs cannot be sued for adverse side effects caused by products that they did not themselves design, the US Supreme Court ruled on Monday (24 June).



In a five-to-four decision, the justices found in favour of Mutual Pharmaceutical, overturning a US\$21m award against it after a woman suffered horrific burns after using an anti-inflammatory in 2004.

Generic drugs are copies of drugs already developed by other firms and approved by state regulators and Mutual argued that any faults in the product are thus not its responsibility.

In his written opinion, conservative Justice Samuel Alito said the court had reached its finding "reluctantly", noting the "tragic" circumstances of the case which had left the victim "severely disfigured" and "nearly blind."

But he ruled it was impossible for manufacturers "to comply with both state and federal law. New Hampshire's warning-based design-defect cause of action is pre-empted with respect to FDA-approved drugs sold in interstate commerce," the panel ruled.

"Generic manufacturers are also prohibited from making any unilateral changes to a drug label," it added.

In the case before the court, plaintiff Karen Bartlett suffered severe burns and pain and several months in a coma after using an anti-inflammatory to treat a sore shoulder.

Source: AFP via I-Net Bridge