Bartlett vs. mutual pharmaceutical: case brief and analysis research paper sample...

Education, Discipline

\n[toc title="Table of Contents"]\n

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Mutual Pharmaceutical vs. Bartlett: Case Brief and Analysis

Facts about the case

Procedural history

Bartlett initiated a suit against the manufacturer of Sulindac; Petitioner Mutual Pharmaceutical for various discrepancies including, fraud, design defect, failure to warn, breach of warranty, manufacturing defect, and negligence. Even so, Bartlett's allegations, which were the purported factual elements that would warrant a legal action, were dismissed based on the notion that they had not doubtful material issues of fact (Shilling, 2012). Nonetheless, Bartlett's singled out his complain to one allegation, which aligned with the notion that Sulindac was unduly detrimental for consumers. This was primarily accredited to the fact that this medication poses various risks, which outweighed its benefits. Bartlett presented her allegations against Mutual in a fourteen day trial, which took place in August to September 2009. Worth noting is the fact that Bartlett's allegations were supported by a pharmacologist, who acted as his core witness. With use of

various data including incident reports, the pharmacologists justified that indeed Sulindac increased the prevalence of Toxic Epidermal Necrolysis and Stevens-Johnsons Syndrome than other medications (King, 2003). In addition, further justifications were received from a burn surgeon who testified for Bartlett. The surgeon alleged that Sulindac had deficiencies in its design.

Supreme Court Decision

Upon review of the case facts drawn from the Lower Court Proceedings, the Supreme Court ruled 5-4 in support of Mutual. As such, this decision reversed the First Circuit Court. This Decision was arrived at on the premise that the state law design-defect allegations that focus on the competence of drugs caveats are pre-empted by the federal regulations. Two different dissents were drawn on this case, but, nevertheless, the majority opinion was enjoined by four justices (Shilling, 2012).

Analysis

Implications related to labeling and liability of generic drugs

Certainly, this case poses a wider implication on the design defect claims, which will have a direct influence in liability and labeling of generic drugs. With regards to labeling, Bartlett’s claims laid focus on the labeling inadequacies. While it is true that federal laws and basic logic shows that Mutual could not have tampered with the labeling or composition of Sulindac, it is crucial to note that there is a possibility that Mutual may have redesigned Sulindac in order to suit FDA’s design-defect regulations (Shilling, 2012).

With regards to liability, Mutual’s case queries if there is a possibility that a federal law could preempt state law claims on the notion that generic drugs manufacturers is to blame for injuries precipitated by its drug products. It is also crucial to note that liability may have occurred due to issues of misbranding. Certainly, this case changed the scope of various issues aligned with labeling and liability.

FDA rules and regulations on labeling of generic drugs

Labeling of generic drugs in the United States is regulated by the FDA. As such, there are certain regulations aligned with labeling of generic drugs. More importantly, FDA must approve the names to be labeled on generic drugs with reference to the original drugs. As such, the generic drugs must contain similar contents and strengths, which should be labeled accordingly (Crosse, 2010). Similarly, the labeling of generic drugs must be relatively similar to the labeling of the approved drug. Overall, FDA carries out stringent inspection of the generic drugs before their release for use in the market.

References

Crosse, M. (2010). Food and Drug Administration: FDA Faces Challenges Meeting Its Growing Medical Product Responsibilities and Should Develop Complete Estimates of Its Resource Needs. Boston: DIANE Publishing.

King, L. A. (2003). The misuse of drugs act: A guide for forensic scientists. Cambridge: Royal Society of Chemistry.

Shilling, D. (2012). Lawyer's desk book, 2013. S. l.: Kluwer Law International.

Voet, M. A. (2011). The generic challenge: Understanding patents, FDA and pharmaceutical life-cycle management. Boca Raton, Fla: BrownWalker Press.