# Supreme Court to Hear Generic Drug Lawsuit Over Design Defects



By: Irvin Jackson | Published: December 3rd, 2012

The U.S. Supreme Court has decided to review a generic drug lawsuit, which deals with the question of whether manufacturers can be held liable for selling dangerous and defectively designed generic medications.

On Friday, the nation's highest court agreed to hear an appeal stemming from a personal injury and product liability lawsuit brought by Karen Bartlett, of New Hampshire, against Mutual Pharmaceutical co., a subsidiary of Takeda Pharmaceuticals.

Bartlett alleges that she developed a severe skin reaction, known as **Stevens-Johnson Syndrome (SJS)**, after taking a generic non-steroidal anti-inflammatory (NSAID) called sulindac.

As a result of the condition, Bartlett was hospitalized for 70 days, with 50 of those days were spent in a burn unit. She had multiple surgeries and two major septic shock episodes that were allegedly caused by side effects of the generic drug, which has left her with burns over 65 percent of her body and permanently blinded.

Following trial in December 2004, Bartlett was awarded $21 million by a jury, which found that Mutual's sulindac medication was responsible for the development of Steven's-Johnson Syndrome.

Mutual Pharmaceutical has maintained that it should not be liable for the allegedly defective design of the generic drug, arguing that they should be immune from liability, so long as the medication used the same warning label as the original brand-name version of the drug, which is marketed by Merck as Clinoril.

The generic drug maker has argued that the controversial 2011 Supreme Court decision in *Pliva v. Mensing* establishes that the plaintiff's design defect claims should have been pre-empted by federal regulations on generic drug makers.

In ***Pliva v. Mensing***, the Supreme Court ruled 5-4 down ideological lines that generic drug makers can not be held liable for failing to warn about risks associated with their medications, even if they knew or should have known that the warning label is inadequate. The majority of the Court determined that FDA regulations that require generic drug labels to match their brand-name equivalents made it impossible for generic drug makers to comply with both federal and state law.

As a result of the Supreme Court decision, thousands of product liability lawsuits pending against the manufacturers of generic medications have been **dismissed or at risk of being thrown out**, including lawsuits over generic Reglan, Accutane, Darvocet, Zocor and others.

On November 30, the U.S. Supreme Court court **granted certification (PDF)** of an appeal from the First Circuit to evaluated whether the lower court erred when it held that federal law does not pre-empt state law design defect claims involving generic drugs, as opposed to failure to warn claims addressed in *Pliva*.

Plaintiffs have argued that the conflict between such claims and the federal laws governing generic drug design can be avoided if the manufacturers of the generic equivalents simply stop making their products.

In attempt to further insulate themselves from liability lawsuits stemming from generic drugs they make, a number of generic drug manufacturers have filed briefs in the case.

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