

Supreme Court ruling supports generic drug makers

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The US Supreme Court ruled Tuesday that generic drug makers can challenge big-name pharmaceutical firms in court to stop them from broadening the scope of their patent descriptions.

The measure overturns a 2010 appeals court ruling and confirms an earlier decision by a federal judge that ordered the US subsidiary of Danish laboratory Novo Nordisk to narrow the description of its patent on repaglinide, an anti-diabetes drug sold under the name Prandin.

Caraco Pharmaceutical Laboratories, the US subsidiary of the Indian firm Sun Pharmaceutical Industries, is seeking to produce a [generic version](#) of Prandin.

However Novo Nordisk amended the wording of his patent to extend it, and block the Caraco's request to the [US Food and Drug Administration](#) (FDA) to produce a generic version of the drug.

The FDA cannot approve the sale of a drug that breaks [patent protection](#) laws.

In a unanimous decision by the nine Supreme Court justices, Justice Elena Kagan wrote that "a generic company can employ the counterclaim to challenge a brand's overbrand use code."

"We accordingly hold that Caraco may bring a counterclaim seeking to 'correct' Novo's use code," the ruling read.

"While we are disappointed with the decision," said James Shehan, a senior official with Novo Nordisk Inc, USA, "it appears the Supreme Court has held only that Caraco may challenge the use code narrative for Novo Nordisk's patented method of treating diabetes with repaglinide in combination with metformin.

"Novo Nordisk's use code narrative is, and has always been, correct, and we are confident that further proceedings will show Caraco's challenge to the use code narrative is meritless," Shehan said.

In 2011, US sales of Novo Nordisk drugs Prandin and PrandiMet totaled \$175.96 million (about one billion Danish kroner), according to the firm.

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