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## Government gives boosts to generics

A new ruling by the highest court will affect the way future patent deals are made. A decision by the U.S. Supreme Court will allow **MedImmune** Inc. to challenge a patent owned by **Genentech** Inc., even though MedImmune continues to pay royalties to Genentech. The patent at issue is alleged by Genentech to cover MedImmune's respiratory drug **Synagis**, a product that has accounted for more than 80% of MedImmune revenue since 1999, generating more than \$1 billion in 2005.

"This decision will alter the structure of future deals," says Allen Baum, president of **Licensing Executives Society** for USA & Canada Inc. ([usa-canada.les.org](http://usa-canada.les.org)), a professional society engaged in the transfer, use, development, manufacture, and marketing of intellectual property. "This changes the rules of engagement."

The Supreme Court decision allows MedImmune to challenge the Genentech ([gene.com](http://gene.com)) patent and avoid the risk of incurring treble damages or an injunction. The decision reverses prior rulings holding that a patent licensee had to stop making royalty payments before a court would take the case. MedImmune has been paying the royalties under protest.

"Under the right circumstances, this decision gives licensees the ability to take a license under a patent and later challenge coverage, validity, and enforceability with impunity," Mr. Baum says. "Companies with big continuing royalty obligations will look at this decision closely and think twice about whether they should keep paying without a challenge."

Executives with MedImmune believe that by granting the company's appeal, the U.S. Supreme Court has brought clarity to the patent-litigation process — specifically, the use of declaratory judgments by licensees of questionable patents.

The Supreme Court's decision means MedImmune ([medimmune.com](http://medimmune.com)) is free to pursue its complaint regarding non-infringement, invalidity, and unenforceability of the Cabilly II patent. MedImmune intends to do so vigorously, and executives are confident that the company's position will prevail.

The 1984 Hatch-Waxman Act sought to permit the resolution of patent disputes before the expiration of patents to accelerate consumer access to affordable medicines. In 2003, Congress recognized that some brand-drug companies had sought to delay this infringement litigation, forcing generic companies to decide between launching a product with the risk of being sued and foregoing launching the product at all. In response, Congress expressly provided generic companies with the ability to bring declaratory judgment actions to promptly resolve patent disputes.

The Generic Pharmaceutical Association supported MedImmune regarding this case. "This decision is a victory for consumers and the entire health-care system in the fight to reduce health-care costs while improving care," according to Kathleen Jaeger, the president and CEO of the Generic Pharmaceutical Association ([gphaonline.org](http://gphaonline.org)). "By striking down the Federal Circuit's 'reasonable apprehension' test, the Supreme Court has ruled in favor of American consumers by making it harder for brand companies to delay generics from coming to

market."