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PRESS RELEASE

WRF Wins Appeal Protecting the Rights of Holders of New Drug Applications

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Wiley Rein & Fielding LLP won an important appeal on behalf of its clients Pfizer Inc. and Greenstone Ltd., ensuring that holders of approved New Drug Applications (NDAs) are able to compete immediately on an unbranded basis in the multi-source drug market without interruption or regulatory delay. The June 3, 2005 unanimous decision by the United States Court of Appeals for the District of Columbia Circuit upheld an earlier statutory interpretation by the Food and Drug Administration (FDA) and reinforced Congress's balance of incentives expressed in the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act.

Teva Pharmaceutical Industries Ltd., which holds an approved Abbreviated New Drug Application (ANDA) for gabapentin, sought to keep NDA holder Pfizer and its subsidiary Greenstone from marketing gabapentin at a competitive price during the first 180 days of the multi-source market for that drug. Both FDA and the United States District Court for the District of Columbia rejected Teva's attempt to use 21 U.S.C. §355(j)(5)(B)(iv) as a restriction on NDA holders, which are regulated under a different section of the Act.

The D.C. Circuit affirmed those decisions, writing that § 355(j)(5)(B)(iv) "says nothing about how the holder of an approved NDA may market its drug." The court added, "Congress sought to strike a balance between incentives, on the one hand, for innovation, and on the other for quickly getting lower-cost generic drugs to market. Because the balance struck between those competing goals is quintessentially a matter for legislative judgment, the court must attend closely to the terms in which the Congress expressed that judgment."

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Wiley Rein & Fielding attorneys Bert W. Rein, Karyn K. Ablin, William A. McGrath and Mark B. Sweet handled the case.

View court opinion.