

Wiley Rein & Fielding Client Mylan Wins Significant Patent Dispute as Appeals Court Upholds Ruling on Oxybutynin

September 7, 2006

WRF patent attorneys James H. Wallace, Jr., John B. Wyss, Kevin P. Anderson and Robert J. Scheffel have successfully represented Mylan Laboratories Inc. in the appeal of an earlier patent dispute against Johnson & Johnson's Alza Corporation as described in the Mylan press release that follows.

[View the Federal Circuit opinion.](#)

[Mylan Press Release:](#)

U.S. Court of Appeals Rules in Favor of Mylan in Oxybutynin Patent Litigation-Mylan Plans to Immediately Launch Upon Final FDA Approval

PITTSBURGH, Sept. 7 /PRNewswire-FirstCall/-Mylan Laboratories Inc. (NYSE: MYL) today announced that the U.S. Court of Appeals for the Federal Circuit upheld a district court decision that Mylan's Oxybutynin products do not infringe a patent for DITROPAN XL® and that the patent was invalid. Mylan has received tentative approval and is currently awaiting final approval from the United States Food and Drug Administration (FDA) for its 5 and 10 mg strengths of Oxybutynin. Mylan is the first generic company to file Abbreviated New Drug Applications (ANDAs) for these two strengths, and will therefore be eligible for 180-days of market exclusivity upon commercial launch. The 5 and 10 mg strengths represent more than 80% of the approximately \$380 million in U.S. sales during the 12-month period ended June 30, 2006, according to IMS. The Company also entered into exclusive supply agreements with Ortho-McNeil

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Practice Areas

Copyright
Hatch-Waxman Act Litigation
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Pharmaceuticals, Inc. and Alza Corporation which would allow for Mylan to launch all three strengths of DITROPAN XL.

Robert J. Coury, Mylan's Vice Chairman and Chief Executive Officer commented: "We are pleased with the appellate court's decision and expect to launch all three strengths of this product. Oxybutynin is the latest in a series of difficult to formulate products that Mylan over the many years has been able to successfully develop."
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Mylan Laboratories Inc. is a leading pharmaceutical company with three principal subsidiaries: Mylan Pharmaceuticals Inc., Mylan Technologies Inc. and UDL Laboratories Inc. Mylan develops, licenses, manufactures, markets and distributes an extensive line of generic and proprietary products.

This press release includes statements that constitute "forward-looking statements," including with regard to the final approval and launch of strengths of Oxybutynin and market exclusivity for the products. These statements are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Because such statements inherently involve risks and uncertainties, actual future results may differ materially from those expressed or implied by such forward- looking statements. Factors that could cause or contribute to such differences include, but are not limited to: unexpected regulatory or other delays; the risk that the product will not receive final FDA approval; and the other risks detailed in the Company's periodic filings with the Securities and Exchange Commission. The Company undertakes no obligation to update these statements for revisions or changes after the date of this release.

Source: Mylan Laboratories Inc.

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