

Chad Landmon Discusses Astellas Court Loss with Generic Line

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ATTORNEYS

Landmon, Chad

PRACTICE AREAS

Intellectual Property

Generic Line

Astellas Pharma U.S. failed during August 2009 to win a court ruling that might have helped fend off generic competition for its Prograf immunosuppressant drug. Astellas Pharma filed a citizen petition in September 2007, asking FDA to establish more stringent standards for companies seeking approval of generic versions of Prograf, including additional bioequivalence studies. FDA subsequently rejected the petition, forcing Astellas to seek a temporary restraining order and preliminary injunction in court to prevent the FDA from approving a generic version of Prograf. During August 2009, Judge Ricardo Urbina of the U.S. District Court for the District of Columbia issued a one-page order denying the company's request. Chad Landmon, chair of the FDA practice at Axinn, spoke with Generic Line about the case, saying, "The decision may have a wider impact, potentially with other drugs with a narrow therapeutic index. This decision shows reluctance at FDA to change its bioequivalence standards for a specific product and to critically evaluate challenges to the standard bioequivalence standards."

The article, entitled, "Astellas Loses Court Bid To Fend Off Competition," was published by Generic Line on August 19, 2009. [Click here for a copy of the article:](#)