News Release

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2009 Massachusetts Avenue, N.W.
Washington, D.C. 20036
202.588.0302

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COURT URGED TO RESPECT RIGHTS OF DRUG FIRMS IN PATENT CHALLENGES

(Mylan Pharmaceuticals, Inc. v. Thompson)

The Washington Legal Foundation (WLF) this week urged the U.S. Court of Appeals for the Federal Circuit not to permit those challenging patents held by pharmaceutical companies to circumvent the procedural protections that Congress granted to patent holders when it adopted the Hatch-Waxman Act in 1984.

In a brief filed in *Mylan Pharmaceuticals v. Thompson,* WLF argued those challenging patents should be required to raise their claims in connection with the normal procedures established for such challenges; they should not be permitted to circumvent those procedures with novel legal claims, such as suits challenging a drug company's decision to list a patent in the "Orange Book" maintained by the Food and Drug Administration (FDA).

"WLF takes no position on the merits of the patent dispute in this or any similar disputes between 'pioneer' drug manufacturers (who initially develop a drug) and generic manufacturers (who wish to market a drug after its patent has expired)," said WLF Chief Counsel Richard Samp after filing WLF's brief. "Nonetheless, the procedures adopted by Congress for resolving such disputes were intended by Congress protect the rights of both groups. Unless the courts adhere strictly to those procedures, they will be upsetting Congress's carefully crafted balance," Samp said.

The case involves efforts by Bristol-Myers Squibb Co. (BMS) to assert patent rights in connection with an anti-anxiety drug known as buspirone. Just before BMS's initial patent was set to expire last November, the Patent and Trademark Office granted BMS a new, method-of-use patent that incorporated recent BMS discoveries regarding treatment of anxiety disorders. BMS submitted this new patent to the Food and Drug Administration (FDA) and persuaded FDA to list the patent in its Orange Book. The result of that listing was to delay approval of Abbreviated New Drug Applications (ANDAs) filed by generic manufacturers who hoped to market buspirone as soon as BMS's initial patent expired.

The Hatch-Waxman Act sets forth procedures to resolve disputes between pioneer and generic manufacturers regarding whether existing patents should prevent the generic manufacturer from selling a patented drug.. Those procedures state that the generic manufacturer must file notice with FDA of its intent to market the drug -- based either on a claim that the patent is invalid or that its sales will not infringe the patent. Once that notice is filed, the patent holder has 45 days to file a patent infringement suit. If no such suit is filed within 45 days, then the generic manufacturer is permitted to file its own suit, seeking a declaration that the patent is invalid and/or not infringed. In both instances, the FDA declines to approve marketing of the generic drug until the patent validity litigation is resolved.

In this instance, Mylan Pharmacauticals, Inc. (one of the generic manufacturers seeking to market buspirone) chose not to follow the procedures set out in Hatch-Waxman. Rather, within days of BMS's listing of its new patent in the Orange Book, Mylan filed suit against BMS and FDA in federal district court, alleging that BMS had acted improperly in submitting the patent for listing. Mylan thereby sought to avoid the mandatory 45-day waiting period before filing a suit directly challenging the patent. The district court determined that Mylan's suit stated a cause of action, and it proceeded to grant a preliminary injunction requiring BMS to request deletion of its patent from the Orange Book. BMS has appealed that decision to the Federal Circuit.

In its brief, WLF takes no position on the underlying patent dispute between Mylan and BMS. Rather, WLF argues that federal law does not grant Mylan a private right of action to vindicate its alleged rights. WLF argues that the suit is an effort by Mylan to enforce provisions of the Federal Food, Drug, and Cosmetics Act (FDCA) (whose provisions govern administration of the Orange Book), but that federal law explicitly forbids anyone other than FDA from enforcing the FDCA. *See* 21 U.S.C. § 337(a). WLF further argues that if the suit is viewed as an effort by Mylan to determine whether it has infringed BMS's patent, the suit must be dismissed as premature because less than 45 days have elapsed since Mylan announced to BMS its intent to challenge the BMS patent.

WLF is a public interest law and policy center with members in all 50 states. WLF devotes a substantial portion of its resources to defending the property rights of the business community, including patents and other intellectual property.

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For further information, contact WLF Chief Counsel Richard Samp, (202) 588-0302.