Press Release

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COURT URGED TO PRESERVE PHARMACEUTICAL PATENT RIGHTS

(Pfizer, Inc. v. Dr. Reddy's Laboratories, Inc.)

The Washington Legal Foundation (WLF) this week urged the U.S. Court of Appeals for the Federal Circuit to overturn a district court decision that threatens to cut short patent rights granted to pharmaceutical companies under the Hatch-Waxman Act.

In a brief filed in *Pfizer, Inc. v. Dr. Reddy's Laboratories, Inc.,* WLF argued that by assigning too restrictive a definition to what constitutes the chemical substance protected by a patent, the district court undermined patent rights and thereby significantly reduced the economic incentives for companies to invest the vast sums necessary to develop new life-saving products. WLF filed its brief with the assistance of Philip A. Lacovara, Donald M. Falk, Michael O. Warnecke, Joseph A. Mahoney, and Thomas R. Stiebel of the law firm of Mayer Brown Rowe & Maw.

"When Congress adopted the Hatch-Waxman Act, it intended to balance the rights of `innovator' 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. "The district court decision threatens to undermine that balance by depriving innovator drug manufacturers of most of the benefits granted to them under Hatch-Waxman," Samp said.

The case involves the drug amlodipine, which Pfizer markets under the trade name Norvasc. Pfizer holds a patent for amlodipine. Nonetheless, a generic manufacturer, Dr. Reddy's Laboratories, Inc. ("Reddy"), seeks to market a generic form of amlodipine. After Reddy announced its intentions, Pfizer filed a patent infringement suit against Reddy in federal district court in New Jersey. Reddy contends that its product does not infringe the Pfizer patent because, although it includes the same active ingredient, that ingredient is combined with an "addition salt" that is different from the salt used in Norvasc. The case turns on the meaning provisions in the Hatch-Waxman Act that relate to patent term extensions.

Adopted in 1984, the Hatch-Waxman Act contains some provisions of benefit to generic drug companies and other provisions of benefit to innovator drug companies. The Act benefited generic companies by creating the Abbreviated New Drug Application (ANDA) procedure, which greatly streamlined the process by which generic manufacturers can receive FDA approval to market generic copies of pioneer drugs. The Act benefited innovator manufacturers by granting patent-term extensions (the "PTE provisions"), as partial recompense for the fact that a manufacturer obtains no benefit from its patent during the period following the issuance of the patent and prior to marketing authority being granted by the Food and Drug Administration.

The district court held that the PTE provisions only extend patent protection to compounds that are exact duplicates of the product approved by FDA. Because Reddy's generic product combines the active ion in amlodipine with a different "addition salt," the district court held that the Reddy product was not an exact duplicate and thus did not infringe Pfizer's extended patent.

In its brief, WLF argued that the district court misinterpreted the PTE provisions of the Hatch-Waxman Act. More importantly, WLF argued, the district court decision will have devastating effects on R&D efforts because it effectively nullifies all patent term extensions. WLF noted that almost all active ingredients in pharmaceuticals are combined with a salt or ester to improve stability and solubility. Because the most common addition salts are largely interchangeable, WLF argued, generic manufacturers will almost always be able to find a way to combine the active ion of the pioneer drug with a salt other than the one used by the patent holder -- and thus, under the district court's reasoning, could market its generic product while the extended patent term is still in effect. WLF argued that that result undermines congressional intent.

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. A copy of the brief is posted on WLF's web site, www.wlf.org.