Washington Legal Foundation
Advocate for freedom and justice®
2009 Massachusetts Avenue, NW
Washington, DC 20036
202.588.0302

August 2, 2007

APPEALS COURT STRIKES DOWN D.C. DRUG PRICE CONTROL LAW

(Biotechnology Industry Organization v. District of Columbia)

The U.S. Court of Appeals for the Federal Circuit yesterday struck down a District of Columbia law that imposes strict price controls on prescription drugs still covered by a patent, a decision that will likely protect critical pharmaceutical research and development.

The decision was a victory for the Washington Legal Foundation (WLF), which filed a brief in the case, *BIO v. District of Columbia*, urging that the law be struck down. The court agreed with WLF that the law is preempted by federal patent laws because it interferes with the objective Congress sought to achieve in adopting the patent laws – namely, to encourage innovation by rewarding those who expend the resources necessary to develop new products. The court held that the law (the "D.C. Act") stands as an obstacle to Congress's objectives because, by depressing prices, it prevents drug patent holders from reaping the rewards Congress intended to bestow.

"The D.C. government sought to tinker with the delicate balance crafted by Congress in the patent law system for short-term relief from higher drug prices," said WLF Chief Counsel Richard Samp after reviewing the court's decision. "But if more such laws were adopted, the loser in the long run would be American patients. Price controls lead to decreased spending on pharmaceutical research and development, with the inevitable result that fewer drugs will be developed," Samp said.

WLF filed its brief on behalf of itself; the Kidney Cancer Association, a group that advocates on behalf of patients suffering from kidney cancer; and the 60 Plus Association, a group that advocates on behalf of senior citizens.

The case involved D.C.'s Prescription Drug Pricing Act of 2005, which prohibited sales of patented prescription drugs at an "excessive price." The D.C. Act provided that a prima facie case of excessive pricing can be established "where the wholesale price of a patented prescription drug" sold in D.C. was "30% higher than the comparable price" in either the United Kingdom, Germany, Canada, or Australia. It permitted any citizen who felt aggrieved by the price charged for drugs to file suit against the drug manufacturer as a private attorney general.

The Biotechnology Industry Organization and the Pharmaceutical Research and Manufacturers of America, two industry associations, filed suit against the Act in 2005 in federal district court in the District of Columbia, alleging that the Act: (1) violated the Commerce Clause because it sought to control prices charged in sales occurring wholly outside D.C.

(between drug manufacturers and wholesalers); and (2) was preempted by federal patent law. Agreeing with the plaintiffs on both of those claims, the district court granted a permanent injunction against enforcement of the D.C. Act. The District of Columbia government appealed the preemption portion of that decision to the U.S. Court of Appeals for the Federal Circuit (which has jurisdiction over all appeals in patent-related cases). Yesterday's decision affirmed the district court ruling.

The Federal Circuit's decision agreed with WLF's argument that the D.C. Act conflicts with federal patent law and thus cannot stand. The court held that Congress has carefully calibrated the extent of the rewards that ought to be conferred on successful inventors; that calibration has encompassed such steps as changing the number of years a patent stays in effect, adopting procedures that allow a drug manufacturer to obtain an extension of the patent term under certain circumstances, and adopting procedures that allow generic drug manufacturers to bring competing drugs to market relatively quickly. The court agreed with WLF that such measures indicate that Congress was attempting to strike a careful balance between rewarding successful inventors and providing low-cost drugs to consumers. The court held that State drug price controls undermine congressional intent by upsetting Congress's carefully constructed balance.

WLF also argued that the D.C. Act, if allowed to take effect, would have devastating long-term adverse effects on health care in this country. WLF argued that price controls on drugs stifle pharmaceutical research, with the inevitable result that fewer life-saving drugs would be developed. WLF noted that, on average, it takes anywhere from $800 million to $1.7 billion in research and development costs to get a drug approved for use in the U.S. Drug companies would be unwilling to invest such massive sums if State drug price controls deprived them of any assurance that they could recover those costs by utilizing the market advantages provided them under the patent system, WLF argued.

WLF is a public interest law and policy center with supporters in all 50 States, including many in the District of Columbia. It devotes a significant portion of its resources to advocating for improvements in health care.

* * *

For further information, contact WLF Chief Counsel Richard Samp, (202) 588-0302. A copy of WLF's brief is posted on its web site, www.wlf.org.