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CLIENT ALERT

District of Columbia Law Limiting Pharmaceutical Prices Held Unconstitutional

January 4, 2006

by David Hammond

The Federal District Court for the District of Columbia has enjoined a District of Columbia law that permitted lawsuits against pharmaceutical manufacturers for patented drugs sold at allegedly "excessive prices." The lawsuit was brought by the Pharmaceutical Manufacturers and Research Association and the Biotechnology Industry Organization and the Biotechnology Industry Association. *Pharmaceutical Research and Manufacturers Association v. District of Columbia*, Civ. No. 05-2015 (RJL) (Dec. 22, 2005).

Under the law, "affected" parties could bring suit for damages and injunctive relief against manufacturers or licensees of patent drugs sold at an "excessive price" – a term which was not defined under the law. Instead, the law allowed a *prima facie* showing of an excessive price by demonstrating that the "wholesale price of a patented prescription drug" sold in the District of Columbia is "30% higher than the comparable price" in either the United Kingdom, Germany, Canada, or Australia if the drug is also protected "by patents or other exclusive marketing rights" in those countries.

The Court found that the District of Columbia law violated the United States Constitution's Supremacy Clause because it was implicitly preempted by a federal law – the Patent Term Restoration Act of 1984 (21 U.S.C. § 355 *et seq.*) – that grants pharmaceutical manufacturers certain exclusive market rights beyond the original patent term. The Court found that the purpose of the Patent Term Restoration Act was to create a new incentive for increased expenditures for research and development of certain products which are subject to premarket approval. The District of Columbia law impermissibly conflicted with the federal law because "[p]unishing the holders of pharmaceutical patents in this manner flies directly in the face of a system of rewards calculated by Congress to insure the continued strength of an industry vital to our national interests."

The Court also found that the District of Columbia law violated the Interstate Commerce Clause of the United States Constitution because it "effectively seeks to regulate transactions that occur wholly out of state." The Court found that there was "no question that the D.C. Act was intended to and will control out-of-state conduct." The Court also noted that although no other state has adopted a similar statute, "it takes little imagination to envision the harm to interstate commerce that could be caused by the domino effect of similar legislation being adopted in many, or every, state." Such a result, according to the Court, could produce a "race to the bottom" to set the lowest percentages above the foreign wholesale price in the four designated countries. The Court concluded that the District of Columbia law was a "per se invalid extraterritorial reach in violation of the Commerce Clause and must therefore be additionally struck down as unconstitutional on an as applied basis."

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