Legal Backgrounder

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DRUG PRICE CONTROL FAILS CONSTITUTIONAL TEST

By

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Allowing importation of low-priced foreign drugs has been described as a roundabout way of importing foreign price controls. The District of Columbia tried a simpler route: it passed a law *directly* importing foreign price controls, without the foreign drugs. And because the D.C. law targets *non-retail* prescription drug sales that typically occur outside the District, the imported price controls could reach many sales throughout the U.S.

At least for now, the nation's capital will not become the port of entry for foreign price controls on prescription drugs. In a recent decision, the U.S. District Court for the District of Columbia blocked enforcement of the price control law, known as the Prescription Drug Excessive Pricing Act of 2005. *Pharmaceutical Research and Mfrs. of America v. District of Columbia*, 406 F. Supp. 2d 56 (D.D.C. 2005). Finding the law an obstacle to achieving the purposes of federal patent laws, the court held that the law violated the Constitution's Supremacy Clause. The court held that the law also violated the Constitution's Commerce Clause as applied to prescription drug sales that occur outside the District. While the decision will not be the last word on these issues (as the District has appealed to the D.C. Circuit), it provides a thoughtful and persuasive analysis of the constitutional questions raised by the District's effort to control prescription drug prices.

The D.C. Prescription Drug Excessive Pricing Act. The D.C. Prescription Drug Excessive Pricing Act of 2005[1] makes it unlawful for a drug manufacturer or licensee, "excluding a point of sale retail seller," to sell a patented prescription drug at a price "that results in the prescription drug being sold in the District for an excessive price." "Excessive pricing" is defined by reference to prices in four "high income countries," *i.e.*, the United Kingdom, Germany, Canada, and Australia. Specifically, a *prima facie* case of excessive pricing exists "where the wholesale price of a patented prescription drug in the District is over 30 percent higher than the comparable price in any high income country in which the product is protected by patents or other exclusive marketing rights." When a *prima facie* case is shown, a defendant has the burden of proving that the price is not excessive "given demonstrated costs of invention, development, and production of the prescription drug, global sales and profits to date, consideration of any government funded research that supported the development of the drug, and the impact of price on access to the prescription drug by residents and the government of the District of Columbia." Because the Act is violated by manufacturer sales that "result in" the drug being sold in the District for an excessive price, it could make manufacturers liable for downstream prices set by others in the distribution chain.

The Act authorizes suits by any person "directly or indirectly affected by excessive prices of patented prescription drugs" (including any organization representing such persons, any person or organization representing the "public interest," and the District government). Violations of the Act can result in "injunctions to

[1]D.C. Act 16-171 (to be codified at D.C. Code §§ 28-4551 *et seq.*).

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enjoin the sales of prescription drugs in the District at excessive prices," fines, treble damages, attorney fees, litigation costs, and any other relief the court deems proper. Thus, the Act authorizes the District government or private attorneys general to sue a pharmaceutical manufacturer for excessive pricing; to make out a *prima facie* case by showing that the drug was sold in the District at prices 30% above those in the United Kingdom, Germany, Canada, or Australia; and to seek injunctive relief and recovery of substantial penalties.

The District Court Decision. The D.C. Prescription Drug Excessive Pricing Act was challenged in separate suits by the Pharmaceutical Research and Manufacturers of America (PhRMA) and the Biotechnology Industry Association (BIO) that were later consolidated.[2] After rejecting the District's argument that the plaintiffs lacked standing to bring a pre-enforcement challenge to the Act, the court found the Act invalid on Supremacy Clause and Commerce Clause grounds, while rejecting the claim that the Act violated the Constitution's Foreign Commerce Clause.[3] The Supremacy Clause and Commerce Clause rulings are discussed below.

The Supremacy Clause Ruling – Preemption by the Federal Patent Laws. The plaintiffs' Supremacy Clause claim was based on the theory that the D.C. price control law was preempted by the federal patent laws regulating pharmaceuticals. The court noted that State laws (including District of Columbia laws) can be impliedly preempted by federal law based on: (1) field preemption (where the federal regulatory scheme is so pervasive as to leave no room for supplementary State laws); or (2) conflict preemption (where compliance with both State and Federal laws is impossible, or where the State law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress").[4] The court found that the District's price control law was an obstacle to achieving the purposes of the federal patent laws in connection with patented pharmaceuticals. While the patent laws were designed to *spur* innovation – by giving inventors the opportunity to recoup their investment in developing a patented product – the D.C. law threatened to undercut that goal by reducing the rewards for innovation in the pharmaceutical sector.

The court focused in particular on the Drug Price Competition and Patent Term Restoration Act of 1984 (commonly known as the Hatch-Waxman Act),[5] which restored part of the patent term lost by pharmaceuticals during the FDA approval process in order "to create a new incentive for increased expenditures for research and development of certain products which are subject to premarket government approval."[6] Finding that the D.C. law created an "unmistakable obstacle" to this goal, the court held that: "Punishing the holders of pharmaceutical patents . . . 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. Ironically, the factors Congress weighed in calculating their system of rewards are the very same factors the [D.C.] Act requires manufacturers to litigate . . . in response to a

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[2]The court also consolidated the ruling on the merits and request for injunctive relief under Federal Rule of Civil Procedure 65(a)(2).

[3]The court did not discuss the Foreign Commerce Clause issue at any length, but stated that because the plaintiffs' Foreign Commerce Clause claim involved a facial challenge to the price control law, they had to establish that "every conceivable application" of the law would violate the Foreign Commerce Clause and could not make such a showing. The court stated that while the law allowed a plaintiff to make out a *prima facie* case of excessive pricing by proving that the wholesale price of a drug was more than 30% higher than the comparable price in one of the four "high income countries," this was an "optional" approach for making out a *prima facie* case; consequently, "to the extent that future plaintiffs are able to establish a *prima facie* case . . . without any reference to the wholesale price of the same drug in *any* foreign country, the statute is *not* facially unconstitutional under the Foreign Commerce Clause." *PhRMA v. District of Columbia*, 406 F. Supp. 2d 56 at 72.

[4]*Id.* at 64-65 (quoting *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941)).

[5]The Hatch-Waxman Act struck a careful balance between the goals of encouraging innovation (by restoring part of the patent term consumed during the FDA approval process, when the manufacturer cannot market the patented pharmaceutical) and facilitating the entrance of generic competitors once the period of patent exclusivity expired. As a result, the opportunity for inventors of patented drugs to recoup their research and development costs during the exclusivity period is particularly important in preserving incentives for innovation, since the possibility of recouping those costs after the exclusivity period would be reduced by the accelerated introduction of generic competitors that would drive down prices.

[6]*PhRMA v. District of Columbia*, 406 F. Supp. 2d at 66 (quoting *Pfizer Inc. v. Dr. Reddy's Laboratories, Ltd.*, 359 F.3d 1361, 1364 (Fed. Cir. 2004), in turn quoting H.R. Rep. No. 98-857, at 15 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2670).

prima facie case."[7] "Because Congress' judgment in this area is supreme," the court concluded, "the D.C. Act is preempted and therefore facially unconstitutional."[8]

Commerce Clause Ruling. The court's Commerce Clause ruling was based on the provisios in the D.C. law imposing liability for excessive pricing on pharmaceutical manufacturers – but not "point of sale retail sellers" – and the plaintiffs' evidence that manufacturer sales generally occur entirely outside the District. Specifically, the plaintiffs presented evidence (apparently undisputed by the District) that their members did not manufacture drugs, maintain headquarters, or operate warehouses in the District; that members generally either sold to wholesalers or large retail chains that were neither headquartered in the District nor had warehouses in the District; and that the only sales by their members to District entities involved a small number of direct sales to hospitals or physicians within the District.[9] Thus, because "the overwhelming majority of plaintiffs' members' sales occur entirely outside the District of Columbia between out-of-state manufacturers and out-of-state wholesalers" and the D.C. Act "explicitly exempts in-state retailers," the Act "effectively seeks to regulate transactions that occur wholly out of state."[10]Stating that the plaintiffs had challenged the D.C. Act as applied to transactions that occur wholly out-of-state (*i.e.*, between a manufacturer and an out-of-state wholesaler or retailer), the court ultimately concluded that the Act "has a *per se* invalid extraterritorial reach in violation of the Commerce Clause as applied to transactions . . . that occur wholly out-of-state."[11]

The court began its analysis by noting that a state statute (including a District statute) directly regulating out-of-state commerce is "*per se* invalid and 'generally struck down . . . without further inquiry.'"[12] The District argued that the Prescription Drug Excessive Pricing Act does not regulate out-of-state transactions~~;~~, since liability is only triggered if a retail sale is made "in the District" at an excessive price. The court disagreed, holding that the Supreme Court in *Baldwin v. G.A.F. Seelig, Inc.*[13] had previously invalidated an analogous statute involving "the effective regulation of an out-of-state transaction triggered by an in-state sale."[14] Baldwin involved a New York law that set minimum prices for sales between in-state milk producers and dealers, and prohibited the in-state sale of milk bought outside New York unless the price paid to the milk producer met New York's minimum price requirement; thus, the only sales that the law literally prohibited were in-state sales. Nevertheless, the Court found that the law effectively regulated out-of-state prices and held that New York had "no power to project its legislation into [another State] by regulating the price to be paid in that State for milk acquired there."[15] Finding the *Baldwin* analogy compelling, the *PhRMA* court reasoned that:

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[7] *PhRMA v. District of Columbia*, 406 F. Supp. 2d at 66-67.

[8] *Id.* at 67.

[9] *Id*. at 61-62, 68.

[10] *Id.* at 68.

[11] *Id.* The court noted that, pursuant to Supreme Court jurisprudence, several circuits have recognized a three-tiered approach to Commerce Clause analysis, which analyzes whether the state statute: (1) directly controls commerce occurring entirely outside the state's boundaries, and thus has a *per se* invalid extraterritorial reach; (2) discriminates against interstate commerce, and thus is subject to strict scrutiny; or (3) regulates evenhandedly, with only incidental effects on interstate commerce, and thus is subject to the balancing test articulated in *Pike v. Bruce Church, Inc.*, 397 U.S. 137 (1970). *PhRMA v. District of Columbia*, 406 F. Supp. 2d at 67-68 n. 12. The court decided that "because the D.C. Act, as applied, has a *per se* invalid extraterritorial reach, it need not address whether the Act, on its face, discriminates against interstate commerce, nor is it necessary to apply the *Pike* balancing test to the facts of this case." *Id.*

[12] *Id*. at 68 (quoting *Brown-Forman Distillers Corp. v. New York State Liquor Authority*, 476 U.S. 573, 579 (1986)).

[13] 294 U.S. 511 (1935).

[14] *PhRMA v. District of Columbia*, 406 F. Supp. 2d at 69.

[15] *Baldwin*, 294 U.S. at 521.

> Like the statute in *Baldwin*, the D.C. Act is triggered by an in-state sale. If a manufacturer's patented prescription drug is never sold in the District, the Act cannot . . . create liability against that manufacturer. But as soon as that drug is sold in the District, the manufacturer's out-of-state sale becomes the Act's primary target. . . . *Baldwin* . . . found this type of regulation – which uses an in-state hook to affect out-of-state conduct – to be . . . in violation of the Interstate Commerce Clause.[16]

The court also rejected the District's claim that the price control law was valid because it was based on the District's police power to regulate matters involving the health and welfare of District residents, holding that a public health exception to the Commerce Clause would "eat up the rule under the guise of an exception."[17] In consequence, the court concluded, "the District's reliance on its police powers cannot, alone, overcome the otherwise unconstitutional reach of the D.C. Act."[18]

Conclusion. State laws that import foreign price controls on patented pharmaceuticals – especially when they affect sales prices in other states, effectively extending the price controls beyond the State's borders – can discourage the investments fueling the medical advances that Americans have grown to expect. Government and private sector studies have found that pharmaceutical price controls can inhibit the development of new drugs,[19] suggesting that price controls can have high costs for people who need better treatment alternatives. Perhaps the most important aspect of the District Court's *PhRMA* decision is that its preemption ruling connects these policy concerns with a legal barrier to State-enacted pharmaceutical price controls: because federal patent laws are designed to reward and encourage pharmaceutical innovation, States may not thwart that goal by reducing the rewards for innovation. Yet the political and budgetary pressures for individual States to "do something" about high drug prices cannot be discounted. The *PhRMA* case suggests that States can go too far in mandating discounts on patented medicines; at some point, constitutional limits place a check on State laws that would confer short-term benefits on the State and its residents at the expense of longer-term advances in medicine.

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[16] *PhRMA v. District of Columbia*, 406 F. Supp. 2d at 69 (footnote omitted). The court also noted that the D.C. Act was not analogous to the Maine statute at issue in *PhRMA v. Walsh*, 538 U.S. 644 (2003), which restricted Medicaid coverage for a manufacturer's drugs unless the manufacturer paid supplemental rebates to Maine. While *Walsh* rejected a Commerce Clause challenge to the Maine law because it did not regulate any out-of-state transaction "either by its express terms or by its inevitable effect," the "inevitable effect of the D.C. Act *is* to regulate the price of out-of-state transactions," as the Act "effectively forces manufacturers to sell at a price less than thirty percent more than the wholesale price . . . in one of four enumerated countries or bear the cost and risk of expensive litigation as to whether their wholesale price 'resulted in' an excessive price by the retailer in the District." *PhRMA v. District of Columbia*, 406 F. Supp. 2d at 71 n.15.

[17] *Id*. at 71 (quoting *Baldwin*, 294 U.S. at 523).

[18] *Id*. (footnote omitted).

[19] *See, e.g.*, "Pharmaceutical Price Controls in OECD Countries: Implications for U.S. Consumers, Pricing, Research and Development, and Innovation," U.S. Department of Commerce, International Trade Administration, Dec. 2004.

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