UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA ,	)	
Plaintiff,	)	
v.	)	**Civ. No. 05-2015 (RJL)**
THE DISTRICT OF COLUMBIA, et al.,	)	
Defendants	)	
BIOTECHNOLOGY INDUSTRY ORGANIZATION,	)	
Plaintiff,	)	
v.	)	**Civ. No. 05-2106 (RJL)**
THE DISTRICT OF COLUMBIA, et al.,	)	
Defendants.	)	

MEMORANDUM OPINION
(December 22 2005) [#2, #6]

On October 12, 2005, Plaintiff, Pharmaceutical Research and Manufacturers of America ("PhRMA"), filed a motion for a temporary restraining order and a preliminary injunction against the District of Columbia, Anthony A. Williams, in his official capacity as Mayor of the District of Columbia, the Office of the Attorney General of the District of Columbia, Robert J. Spagnoletti, in his official capacity as the Attorney General of the District of Columbia, the Office of Documents and Administrative Issuances of the District of Columbia, and Arnold R. Finlayson, in his official capacity as Administrator of the Office

of Documents and Administrative Issuances (collectively the "District"), contending that D.C. Act 16-171, the Prescription Drug Excessive Pricing Act of 2005 (the "D.C. Act" or the "Act"), violates the Supremacy, Commerce, and Foreign Commerce Clauses of the Untied States Constitution. Civil Action No. 05-2015, Dkt. #2. The motion for a temporary restraining order was denied the next day and a briefing schedule was set on October 21, 2005 for the motion for a preliminary injunction. *See id.*, Minute Order dated Oct. 13, 2005 and Dkt. #10.

The same day, PhRMA filed a motion for an order consolidating the merits of the plaintiff's action for a declaratory judgment with its application for a preliminary injunction pursuant to Federal Rules of Civil Procedure 57 and 65(a)(2). *Id.* at Dkt. #9. The District, in turn, filed a motion on October 26, 2005 for expedited discovery from PhRMA. *Id.* at Dkt. #11.

The next day Biotechnology Industry Organization ("BIO") filed its complaint seeking the same declaratory relief as PhRMA against the District. *See* Civil Action No. 05-2106, Dkt. #1. In the interests of judicial efficiency, the actions by PhRMA and BIO were consolidated on November 8, 2005, and the ruling on the merits and prayer for injunctive relief under Rule 65(a)(2) were eventually consolidated. *Id.* at Dkt. #12; Civil Action No. 05-2015, Dkt. #18 and Minute Order dated Nov. 17, 2005. Oral arguments were held on November 23, 2005, and supplemental memoranda were filed on December 1, 2005. Civil Action No. 05-2015, Dkts. #24, 25. Due to conflicting reports from counsel regarding the

calculation of the 30 legislative day review period, the Court issued an Order on December 12, 2005, requiring a statement from each party regarding its best calculation as to the expiration of the 30-day period and an update on what, if anything, Congress did regarding the Act. *Id.* at Dkt. #27. On December 13, 2005, the parties submitted to the Court a joint status report which indicated that the 30-day congressional review period expired on December 9, 2005, and that Congress did not take any action as to the Act. Civil Action No. 05-2015, Dkt #28.

Based on the pleadings, oral arguments, and record, the Court finds the D.C. Act unconstitutional and GRANTS the plaintiffs' claims for declaratory and injunctive relief.[1]

BACKGROUND FACTS

I. Legislative History

The Prescription Drug Excessive Pricing Act of 2005 was initially introduced as legislation to the District of Columbia's City Council (the "Council") on February 1, 2005. 52 D.C. Reg. 1295 (Feb. 11, 2005); Defs.' Mem. of Points and Authorities in Opp'n to Pl.'s Mot. for Prelim. Inj. at 4 (hereinafter "Defs.' Opp'n"). The legislation was an effort by the Council "to restrain the excessive prices of prescription drugs,"[2] D.C. Act § 28-4551(3), which it found to be threatening the "health, safety, and welfare of [the District's] residents."

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[1] This Memorandum Opinion shall constitute the Court's Findings of Fact and Conclusions of Law, pursuant to Rule 52(a) of the Federal Rules of Civil Procedure.

[2] According to the defendants, the D.C. Act is to be codified in the D.C. Official Code §§ 28-4551 *et seq.* (2005 Supp.). For ease and clarity, this opinion will cite to the D.C. Act as it will be codified according to the defendants' pleadings.

Id. at § 28-4551(2).[3] Ultimately, the D.C. Act was passed by the Council on September 20, 2005, and signed on October 4, 2005 by Mayor Williams. PhRMA's Mem. of Points and Authorities in Supp. of Its Mot. for TRO and Prelim. Inj. at 1 (hereinafter "PhRMA's Mot."); D.C. Reg. 9061-63.

The D.C. Act was transmitted to Congress on October 6, 2005 for a required 30-day review period under § 602(c)(1) of the District of Columbia Home Rule Act, D.C. Official Code § 1-206.02(c)(1). Defs.' Opp'n at 5-6. It was published in the *District of Columbia Register* on October 14, 2005, 52 D.C. Reg. at 9061-63, but would not take effect until after the 30-day period of congressional review was completed. 52 D.C. Reg at 9063; D.C. Act 16-171, § 4; *see* D.C. CODE § 1-206.02(c)(3) (1973).[4] It did so on December 10, 2005.

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[3] The purpose and reasoning behind the D.C. Act is specifically set forth within three "Findings" pronounced in Section 4551 of the act:

> (1) The excessive prices of prescription drugs in the District of Columbia is threatening the health and welfare of the residents of the District as well as the District government's ability to ensure that all residents receive the health care they need, and these excessive prices directly and indirectly cause economic harm to the District and damage the health and safety of its residents;
>
> (2) The traditional police powers of the District of Columbia include protecting and promoting the health, safety, and welfare of its residents, regulating monopoly pricing of goods and services, and regulating to assure consumer protection and to prevent and sanction unfair trade practices; and
>
> (3) To promote the health, safety, and welfare of its residents, it is incumbent on the government of the District of Columbia to take action to restrain the excessive prices of prescription drugs through mechanisms that are consistent with District and federal law, including the Constitution.

52 D.C. Reg. at 9061; D.C. Act § 28-4551(1)-(3).

[4] The thirty day period refers to a thirty legislative days, not thirty calender days. A legislative day is a day when either the House of Representatives or the Senate is in session. According to the parties, the thirtieth legislative day was December 9, 2005.

II. The D.C. Act

The D.C. Act specifically makes it "unlawful for any drug manufacturer or licensee thereof, *excluding a point of sale retail seller*, to sell or supply for sale or impose minimum resale requirements for a patented prescription drug *that results in* the prescription drug being sold in the District for an excessive price," D.C. Act § 28-4553(emphasis added), and empowers any "affected party"[5] to bring a suit in the Superior Court of the District of Columbia for damages and injunctive relief against the manufacturers or licensees. *Id.* at § 28-4555. By prohibiting excessive retail sales prices, while excluding retail sellers from enforcement, the Act necessarily directs "affected" parties to target the manufacturers' wholesale prices, and the casual relation, if any, between those wholesale prices and the allegedly "excessive" prices set by retailers that result therefrom.[6]

Although it does not specifically define what makes a price "excessive," the Council did include in the statute a formulaic mechanism as an optional way for a plaintiff to establish a prima facie case of excessiveness. *See* D.C. Act § 28-4554(a). Specifically, a prima facie case of excessive pricing "shall be established where the wholesale price of a patented prescription drug" sold in the District of Columbia is "30% higher than the

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[5] The Act defines "affected party" as "any person directly or indirectly affected by excessive prices of patented prescription drugs, including any organization representing such persons or any person or organization representing the public interest." D.C. Act § 28-4552(1).

[6] The statute does not specifically indicate in a number of places that it is the excessive retail price as opposed to the wholesale price that is being prohibited. However, it is impossible to read the "as results in" formulation in Section 4553 in any other way than to focus on resulting excessive retail prices. Accordingly, the Court interprets the statute as specifically prohibiting excessive retail prices caused by a manufacturer's sale or supply of the drug in question.

comparable price" in either the United Kingdom, Germany, Canada, or Australia, if the drug is protected in those countries "by patents or other exclusive marketing rights." *Id.* Upon doing so, the burden shifts from the affected party to the manufacturer of the patented prescription drug to prove, by a preponderance of the evidence, that the price of the drug, presumably at the retail level, is not excessive. *Id.* at § 28-4554(b). The D.C. Act does not state whether this formulaic approach is the only way to establish a prima facie case that a patented prescription drug is excessive. *Id.*; Prelim. Inj. and Trial on the Merits Hr'g Tr. 9:23 - 12:13 (noting possible different interpretations of the D.C. Act as written). It does specifically provide, however, that once a prima facie case is established the manufacturer of the drug can prove that the price of the drug is not excessive given the cost of inventing, developing, and producing the drug, the global sales and profits from the drug to date, the amount of "government funded research that supported the development of the drug, and the impact of price" of the drug to access to the drug by the District of Columbia government and its residents. D.C. Act § 28-4554(b).

If the manufacturer fails to meet its burden, and a Superior Court judge finds that "excessive pricing" was the "result" of the manufacturers' wholesale price, the judge can issue civil penalties and exercise any of the following additional options: "(1) Temporary, preliminary, or permanent injunctions to enjoin the sales of prescription drugs in the District at excessive prices; (2) Appropriate fines for each violation; (3) Damages, including treble

damages; (4) Reasonable attorney's fees; (5) The cost of litigation; or (6) Any other relief the Court deems proper." D.C. Act § 28-4555(b)(1)-(6).

III. The Plaintiffs

PhRMA is a non-profit organization whose members consist of leading research based pharmaceutical and biotechnology companies who account for "close to 70% of the sales of prescription drugs in the United States." Powell Decl. ¶¶ 2-3; PhRMA's Compl. ¶ 16. PhRMA serves as a "policy advocate" for its members and the pharmaceutical industry before federal and state government entities. Powell Decl. ¶ 4; PhRMA's Compl. ¶ 16. BIO is a large biotechnology organization that consists of more than 1,100 members from around the world. Sachdev Aff. ¶ 5; BIO's Compl. ¶ 13. BIO provides "advocacy, business development, and communications services" for its members and also represents other organizations which are related to the biotechnology field or provide services to the industry. BIO's Compl. ¶ 13; *see* Sachdev Aff. ¶¶ 5-7.

PhRMA's members manufacture and sell patented prescription drugs within the United States from facilities outside of the District of Columbia to wholesalers who are also located, for the most part, outside the District of Columbia. PhRMA's Statement of Material Facts Not in Dispute ¶ 2; Powell Decl. ¶¶ 6-8; *see* Soto Decl. ¶¶ 3, 5; *see* Fish Decl. ¶¶ 3-6. In most circumstances, patented prescription drugs that are manufactured by PhRMA's members are subsequently resold in the District of Columbia by retailers who are exempt from enforcement under the D.C. Act. *Id.* BIO's members manufacture and sell patented

prescription drugs and products which are mainly sold to entities outside of the District of Columbia. Sachdev Aff. ¶¶ 7-10; *see* Bowen Aff. ¶¶ 3-5; *see* Meyers Aff. ¶¶ 3-5. BIO represents companies that maintain patents and create patentable inventions. Sachdev Aff. ¶ 7; *see* BIO's Compl. ¶ 26.

While most of the wholesale sales by plaintiffs occur outside the District of Columbia, members of PhRMA and BIO both occasionally sell a small number of products, drugs, and therapies directly to doctors, hospitals, and pharmacies within the District of Columbia. *See* Powell Decl. ¶ 7("Although PhRMA members supply very limited quantities of patented prescription drugs directly to doctors and healthcare institutions in the District of Columbia, the vast majority of patented prescription drugs that are eventually provided to patients in the United States are initially sold by pharmaceutical manufacturers either to drug wholesalers . . . or to large retail pharmacy chains that warehouse their own drugs . . . "); *see* Sachdev Aff. ¶ 8("The overwhelming majority of therapies produced by BIO members are supplied to customers outside the District of Columbia. Such therapies are rarely supplied directly from BIO members to doctors and healthcare institutions in the District."); *see* Meyers Aff. ¶ 4; *see* Belknap Decl. ¶ 7.

ANALYSIS

I. Standing

As a preliminary matter, the District contends that PhRMA and BIO lack standing to bring a pre-enforcement challenge to the constitutionality of the statute on behalf of their

member companies. *See* Defs.' Post-Trial Br. on Standing at 3-5. The defendants argue, in essence, that the plaintiffs have not submitted any evidence, or affidavits, that show a realistic danger that one of their members will suffer an imminent injury by being sued for violating Section 4553 of the D.C. Act. *Id.* at 7. I disagree.

The burden of establishing standing, of course rests with the plaintiffs. *See Sierra Club v. Envtl. Prot. Agency*, 292 F.3d 895, 900 (D.C. Cir. 2002). An organization can have standing to bring claims on behalf of its members "when: (a) its members would otherwise have standing to sue in their own right; (b) the interest it seeks to protect are germane to the organization's purpose; and (c) neither the claim asserted nor the relief requested requires the participation of individual members in the lawsuit." *Hunt v. Washington State Apple Adver. Comm'n*, 432 U.S. 333, 343 (1977); *see also Truckers United for Safety v. Mead*, 251 F.3d 183, 188-189 (D.C. Cir 2001). In doing so, however, the organization must allege sufficient facts to establish that at least one member is threatened with a specific injury or has suffered an injury in fact. *American Immigration Lawyers Assn. v. Reno*, 18 F. Supp. 2d 38, 50-51 (D.D.C. 1998)(citing language from *Valley Forge Christian College v. Americans United for Separation of Church & State, Inc.*, 454 U.S. 464, 487 n.23 (1982)); *see Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-61 (1992). For the following reasons, the plaintiff organizations have sufficiently demonstrated a realistic danger of imminent injury to one or more of their members.

The Supreme Court, in *Babbitt v. United Farm Workers National Union,* stated that in pre-enforcement challenges one "does not have to await the consummation of threatened injury to obtain preventative relief." 442 U.S. 289, 298 (1979)(quoting *Pennsylvania v. West Virginia*, 262 U.S. 553, 593 (1923))(determining certain claims challenging the Arizona Agricultural Employment Relations Act were justiciable, while others were not); *see Pennell v. City of San Jose*, 485 U.S. 1, 8 (1988)(finding standing to challenge a city rent control ordinance when specificity of injury is not too detailed). Indeed, it is enough to determine "a realistic danger of sustaining a direct injury as a result of the statute's operation or enforcement." *Babbitt*, 442 U.S. at 298.

Plaintiffs contend, in essence, that the danger of one or more of its members sustaining a direct injury is both "realistic" and "imminent" when one considers: (1) The District's finding in the D.C. Act that excessive pricing is threatening the health and welfare of the District's residents, D.C. Act § 28-4551(1); (2) the nature of how the pharmaceutical industry actually operates vis a vis the District (i.e. the wholesale transactions by the manufacturers for those drugs later sold within the District occur overwhelmingly outside of the District), *see* Powell Decl. ¶ 7-8, *see* Sachdev Aff. ¶ 8-9; and (3) the statute's litigation option to establish a prima facie case under Section 4554(b) by simply comparing the wholesale price of the drug sold in the District with the wholesale price of the same drug as sold in one of four "high income" countries abroad (e.g., the United Kingdom, Germany, Canada, and Australia), D.C. Act § 28-4554(b). I agree.

By choosing to exempt retailers of any liability for the excessive price of the drugs they sell, the District has, in effect, overwhelmingly focused its enforcement effort on out of state manufacturers and out of state transactions that "result in" excessive retail prices within the District. By finding that "excessive pricing" already exists in the District and by relying, in part, on a comparison to wholesale prices in certain foreign countries to determine excessive retail pricing within the District, the Council has apparently concluded that some of the wholesale manufacturers who sell their drugs for retail sale within the District are selling them at prices in excess of 30% of the wholesale price abroad and that that price, in their legislative judgment, is resulting in some cases in excessive retail prices within the District.

Accordingly, it is very "realistic" for the plaintiffs in this situation to believe and expect that one or more of their members has set a wholesale price 30% higher than that set for the same prescription drug sold in one of the four designated countries. If so, those manufacturers will unequivocally have to bear the litigation burden, and cost, of demonstrating under Section 4554(b) of the D.C. Act, that notwithstanding the prima facie case, the price set by the retailer is either not excessive or not the "result" of the wholesale price that the manufacturer set for the upstream sale.

Moreover, the vulnerability of those manufacturers to imminent litigation is heightened by the practical reality that any law suit triggered by a price that had been previously set for a wholesale transaction has since been priced for retail sale by a third party

which has neither the incentive, nor risk, to modify this allegedly excessive retail price or withdraw the product from the market so that the manufacturer can avoid suit. As a consequence, manufacturers are essentially defenseless to avoid enforcement suits by either the District or "affected" parties empowered under the statute.

Therefore, for all of these reasons, the Court finds that the plaintiffs have more than sufficiently demonstrated the required standing by an organization suing on behalf of its members to challenge the constitutionality of the D.C. Act.[7]

II. The Supremacy Clause Challenge

PhRMA and BIO each facially challenge the D.C. Act as violative of the Supremacy Clause of the United States Constitution. PhRMA's Mot. at 2, 13, 16-24; BIO's Mot. for Prelim. Inj. (hereinafter "BIO's Mot.") at 2-3. In essence, they contend that the law is preempted by the Supremacy Clause because it is a direct obstacle to the purposes and execution of the federal patent laws relative to manufactured drugs. *See Id.*; *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941). The District disagrees, contending that the D.C. Act is not preempted by the Supremacy Clause since it neither excludes federal patent law, nor serves as an obstacle to the intended purpose of those laws as applied to the manufacturers of prescription drugs. Defs.' Opp'n at 11-19.

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[7] *Lujan* stated that plaintiffs must show that there is a "concrete", personal injury, which is "actual and imminent," and that injury is fairly traceable to the defendant's conduct, and that the injury is likely to be redressed if the relief sought is granted. 504 U.S. at 560-61. The fact that if an injury exists, it is traceable to the District's conduct and that the relief sought in this action would redress that injury is not in dispute, and since this Court does not have any reason to believe that plaintiffs fail to meet these requirements, the Court will not address these two aspects of *Lujan*.

For the following reasons, the Court finds the D.C. Act, as drafted, is a clear obstacle to the accomplishment and execution of the purpose and objectives set by Congress in passing federal patent laws relating to prescription drugs and, therefore, finds it violates the Supremacy Clause of the United States Constitution.

A. Conflict Preemption

The Supremacy Clause of the United States Constitution states that "the Laws of the United States . . . shall be the supreme Law of the Land." U.S. Const. art. VI, § 1, cl. 2. Thus, where Congress legislates within the scope of its constitutionally granted powers, that legislation may displace state law. *Wardair Canada Inc. v. Fla. Dep't of Revenue*, 477 U.S. 1, 6 (1986)(holding that a state tax on aviation fuel did not violate the Commerce Clause of the Constitution and was not preempted by Congress); *Sears, Roebuck & Co. v. Stiffel Co.*, 376 U.S. 225, 229 (1964)(finding that a state's unfair competition law cannot prohibit the copying of a product that is not protected by a patent or copyright because the law "clashed" with the objectives of the federal patent laws).

Where federal legislation contains no specific preemption language, however, it is the duty of the federal courts to inquire whether a implied preemption exists in a given situation. *Gade v. Nat'l Solid Wastes Mgmt. Ass'n*, 505 U.S. 88, 98 (1992)(holding that a state's licensing laws were preempted to the extent that they conflicted with the Occupational Safety and Health Act of 1970). In that regard, two types of implied preemption have been recognized by the courts: field and conflict preemption. *Id.* Field preemption applies to

those situations, unlike here, where the scheme of federal regulation is "so pervasive as to make reasonable the inference that Congress left no room for the States to supplement it." *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947). *Hines* is a classic example of field preemption. 312 U.S. 52. In *Hines*, the Supreme Court found that the immigration system that Congress had enacted in regard to the registration of aliens was enacted in order to create "one uniform national registration system," and that the federal regulation was such that a state law could not be enforced when it interfered with the congressional regulation. 312 U.S. at 73-74.

Conflict preemption, on the other hand, applies to those situations where compliance with both state and federal regulations is either a "physical impossibility,"[8] or, as alleged here, "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Id.* at 67. Plaintiffs contend that the D.C. Act is preempted by the Supremacy Clause because it poses such a conflict to the accomplishment and execution of the very purpose and objectives Congress had in mind when it passed the Patent Term Restoration Act and related non-patent market exclusivity statutes. PhRMA's Mot. at 2, 13, 16-24; *see* BIO's Mot. at 3. How so?

Plaintiffs' argument is premised on its assertion that the federal patent laws and related pharmaceutical market exclusivity laws reflect Congress' considered judgment of the

[8] One such example of conflict preemption in which compliance with both federal law and state law was impossible occurred in *McDermott v. Wisconsin*, 228 U.S. 115 (1913). In *McDermott*, a state law made it criminal to offer for sale syrup that was not labeled in compliance with the state law, even though the syrup offered for sale did meet federal labeling requirements. *Id.* at 124-27. Here, the Supreme Court held that the state law was preempted by the federal regulation. *See id.* 136-37.

economic incentives and protections necessary to best promote the development of new medications. PhRMA's Mot. at 17-18. Indeed, plaintiffs contend that Congress gave pharmaceutical innovation even greater statutory protection than other types of innovation when it passed the Patent Term Restoration Act of 1984, which allowed pharmaceutical manufacturers to extend the terms of their patents and provided certain market exclusivity provisions that insulate manufacturers from generic competition *after* its original patent expires. *Id.* at 17; Patent Term Restoration Act of 1984, 35 U.S.C. § 156 (2005); 21 U.S.C. §§ 355 *et seq.* Unfortunately for the District, even a casual review of the congressional history attendant to these considerable legislative achievements bears out the truth of the plaintiffs' unmistakable assertion.

Congress' regulation of our nation's pharmaceutical industry is grounded in large part in a complex balance of economic forces and regulatory exclusivity designed to encourage and reward the innovation, research, and development of new drugs. Indeed, Congressman Henry Waxman, one of the principle sponsors of the Patent Term Restoration Act, articulated Congress' very purpose behind allowing pharmaceutical patent holders to set a price in their discretion:

> because there is no one else in competition, and as a matter of public policy we, under the patent law, give that protection to the person who has put money into research and development for an innovative and new product. But at some point public policy calls for the free market system competition which will bring about the result of a lower price for the consumer. That is the purpose of the legislation.

130 Cong. Rec. 24,427 (1984)(statement of Rep. Waxman).[9] Not surprisingly, some of the federal courts have also acknowledged the same.

In *Pfizer Inc v. Dr. Reddy's Laboratories, Ltd.*, the Federal Circuit specifically commented on the empirical balance within the Patent Term Restoration Act as follows:

> By restoring a portion of the patent term that is consumed during the approval phase, the incentive to develop and market products that require lengthy pre-marketing approval is intended to be preserved: The purpose of [the Patent Term Restoration Act] is to create a new incentive for increased expenditures for research and development of certain products which are subject to premarket government approval."

359 F.3d 1361, 1364 (Fed. Cir. 2004)(quoting H.R. Rep. No. 98-857, at 15 (1984), *as reprinted in* 1984 U.S.C.C.A.N. 2647, 2670). And on a more general note, the Supreme Court itself has also recognized that the federal patent laws reflect a "carefully crafted bargain" among the various interests at stake. *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 63 (1998); *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 150-51 (1989)(stating that the patent system "embodies a carefully crafted bargain for encouraging the creation and disclosure of new, useful, and nonobvious advances in technology and design in return for the exclusive right to practice the invention for a period of years").

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[9] Congressman Carlos Moorhead, when discussing the Patent Term Restoration Act, stated:

> We have struggled for a long time with this legislation, and most of the things that are in this bill . . . are the result of much effort and work over a long period of time and which resulted in compromises between various industries that are involved, the people that will be affected, the senior citizens of our country, the people who manufacture generics, and the people whose patents need to be protected to guarantee that they can get a recovery on the investment that they have made.

130 Cong. Rec. 24,428 (1984)(statement of Rep. Moorhead).

How then does the D.C. Act's thinly veiled effort to force manufacturers to limit the wholesale price of those drugs to less than 30% more than the wholesale price of the same patented drugs sold in four designated "high income" countries square with the congressional purpose and objectives inherent in the Patent Term Restoration Act? It doesn't!

B. The D.C. Act is an Unmistakable Obstacle to Congress' Objectives

Although well motivated, the D.C. Act was unequivocally designed to force drug manufacturers who sell their products both in the District and in certain foreign countries to either limit the price of their product, or face the consequences of expensive litigation over an undefined standard of "excessiveness" which is likely to vary widely across the spectrum of judges on the Superior Court. Considering the relative ease of the *prima facie* case litigation option provided for in the statute, and the severity of the penalties at the judges' disposal, manufacturers will be hard pressed to chose to roll the dice on the expensive option of convincing a given Court that an application of the factors set forth in Section 4554(b) of the D.C. Act yields a non-excessive assessment or a lack of casual connection between the domestic wholesale price and the retailers' "excessive" price. Such choices give new meaning to that old expression: caught between a rock and a hard place. Most manufacturers who want to continue selling their products in the District will undoubtably do exactly what the City Council wants: adjust their wholesale price to an amount no greater than 30% more than the wholesale price of the same product in the four designated foreign countries. And one need not speculate too long as to the likely collateral consequences

throughout the pharmaceutical industry nationwide that such capitulations would cause. Punishing 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. Ironically, the factors Congress weighed in calculating their system of rewards are the very same factors the Act requires manufacturers to litigate in Superior Court in response to a prima facie case. *See* D.C. Act § 28-4554(b).

In short, using the litigation process to determine on a drug to drug basis the application of a given drug's pricing vis a vis that in a foreign country directly interferes with, and second guesses, the balance set by Congress in the current system of patents and market exclusivity for pharmaceutical products. Moreover, by allowing foreign drug prices to serve as the benchmark by which excessiveness may be determined in this country, the City Council is effectively substituting Congress' regulatory scheme for this industry with the regulatory system that has been formulated by these enumerated foreign countries. Because Congress' judgment in this area is supreme, the D.C. Act is preempted and therefore facially unconstitutional.

III. The Commerce Clause Challenge

Plaintiffs next challenge the constitutionality of the D.C. Act under the Interstate Commerce Clause (the "Commerce Clause") of the United States Constitution. *See* U.S. Const. art. I, § 8, cl. 3. Their challenge can be stated succinctly: The D.C. Act, in direct contravention of the Commerce Clause, effectively seeks to regulate transactions that occur

wholly out of state. Unlike their Supremacy Clause challenge, however, plaintiffs do not facially challenge the Act. *See* Pls.' Reply at 16 & n.15. Instead, plaintiffs merely challenge it as it applies to transactions that occur entirely out of state (i.e., between the manufacturer and an out-of-state wholesaler/retailer).[10] *Id.* The Court will limit its focus accordingly, acknowledging at the outset that it would not otherwise consider this additional constitutional challenge but for the significance of the issues and the clear need, in this case, for judicial efficiency.

A. Impermissible Reach Under the Commerce Clause

The United States Constitution provides that "Congress shall have [the] Power . . . To regulate commerce . . . among the several States." U.S. Const. art. I, § 8, cl. 3. This Grant of power to the national Congress prohibits states (and the District of Columbia[11]) from regulating interstate commerce and enacting legislation that would "offend sister States and exceed the inherent limits of the State's power." *Healy v. Beer Inst.*, 491 U.S. 324, 336 n.13 (1989) (citation omitted).

The Supreme Court has held that a state statute "directly regulat[ing]" commerce occurring beyond the boundaries of that state is *per se* invalid and "generally struck down

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[10] Though plaintiffs argue that *Baldwin v. G.A.F. Seelig, Inc.*, 294 U.S. 511 (1935), discussed below, also applies to transactions between out-of-state manufacturers and entities – such as hospitals and HMOs – located in the District, plaintiffs have not factually demonstrated that any such transactions should be considered to "occur" out of state because of where title passes. Thus, this Court does not reach that particular category of transactions.

[11] The District of Columbia is considered a state for the purposes of the Interstate Commerce Clause. *See generally Electrolert Corp. v. Barry*, 737 F.2d 110 (D.C. Cir. 1984).

. . . without further inquiry."[12] *Brown-Forman Distillers Corp. v. New York State Liquor Author.*, 476 U.S. 573, 579 (1986); *see also Healy*, 491 U.S. at 336 ("[A] statute that directly controls commerce occurring wholly outside the boundaries of a State exceeds the inherent limits of the enacting State's authority and is invalid . . . ."). This is so "regardless of whether the statute's extraterritorial reach was intended by the legislature." *Healy*, 491 U.S. at 336. For the following reasons, this Court finds that the D.C. Act has a *per se* invalid extraterritorial reach in violation of the Commerce Clause as applied to transactions between manufacturers and wholesalers that occur wholly out of state.

As discussed previously, Section 4553 of the D.C. Act makes it unlawful for any drug manufacturer or licensee thereof "to sell or supply for sale or impose minimum resale requirements for a patented prescription drug *that results in* the prescription drug being sold in the District for an excessive price." (emphasis added). Plaintiffs' members manufacture patented prescription drugs wholly outside the District of Columbia and are neither headquartered in the District, nor operate warehouses in the District. PhRMA's Mot. at 25

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[12] Several Circuits have recognized a three-tiered approach to Commerce Clause analysis pursuant to Supreme Court jurisprudence. For example, in *Pharmaceutical Research and Manufacturers of America v. Concannon*, the First Circuit conducted three levels of analysis, asking: (1) whether the state statute directly controls commerce occurring wholly outside the boundaries of a state and thus has a *per se* invalid extraterritorial reach; (2) whether the state statute discriminates against interstate commerce and thus should be subjected to strict scrutiny; and (3) whether the state statute regulates evenhandedly with only incidental effects on interstate commerce and thus should be subjected to the balancing test formulated in *Pike v. Bruce Church, Inc.*, 397 U.S. 137 (1970). *See* 249 F.3d 66, 79 (1st Cir. 2001), *aff'd sub nom. Pharm. Research & Mfrs. of Am. v. Walsh*, 538 U.S. 644 (2003); *see also Pharm. Research & Mfrs. of Am. v. Thompson*, 259 F. Supp. 2d 39, 81 n.27 (D.D.C. 2003). Because this Court finds that 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.

(citing Powell Decl. ¶ 8); BIO's Mot. at 3 (citing Sachdev Aff. ¶ 9; Bowen Aff. ¶ 5; Clark Aff. ¶ 5; Meyers Aff. ¶ 5; Hamm Aff. at ¶ 5). Thus, in practice, plaintiffs' members sell "the overwhelming bulk" of their patented prescription drugs in out-of-state transactions to wholesalers or large retail chains that maintain their own warehousing and retail distribution system. PhRMA's Mot. at 25 (citing Powell Decl. ¶ 7; Marmontello Decl. ¶ 4; Broughton Decl. ¶ 4; Belknap Decl. ¶ 4; Fish Decl. ¶ 4; Soto Decl.¶ 5); *see also* BIO's Mot. at 4 (citing Sachdev Aff. ¶ 9; Bowen Aff. ¶¶ 4-5; Clark Aff. ¶¶ 4-5; Meyers Aff. ¶ 5; Hamm Aff. at ¶¶ 4-5). Like plaintiffs' members, none of these wholesalers or large retail chains have their headquarters in the District, nor do they operate warehouses in the District from which they ship patented prescription drugs. PhRMA's Mot. at 25 (citing Powell Decl. ¶ 8); BIO's Mot. at 3 (citing Sachdev Aff. ¶ 9; Bowen Aff. ¶ 5; Clark Aff. ¶ 5; Meyers Aff. ¶ 5; Hamm Aff. at ¶ 5). Thus, the overwhelming majority of plaintiffs' members' sales occur entirely outside the District of Columbia between out-of-state manufacturers and out-of-state wholesalers. Because the D.C. Act explicitly exempts in-state retailers from liability under the statute, the Act effectively seeks to regulate transactions that occur wholly out of state. *See* PhRMA's Mot. 24-25. The District contends, however, that since liability is not triggered under the Act until a retail sale is made "in the District," *see* D.C. Act § 28-4553, "[t]he Act does not control any out-of-state transaction." Defs.' Opp'n at 24. I disagree.

The Supreme Court in *Baldwin v. G.A.F. Seelig, Inc.*, 294 U.S. 511 (1935), confronted and held unconstitutional a similar situation involving the effective regulation of an out-of-

state transaction triggered by an in-state sale. In *Baldwin*, Justice Cardozo reviewed the New York Milk Control Act, which set minimum prices to be paid by milk dealers to milk producers. *Id.* at 519. Although the majority of milk bought in New York was also produced there, approximately thirty percent of New York's milk supply came from out of state. *Id.* The act at issue in *Baldwin* contained a provision prohibiting "the sale within the state of milk bought outside unless the price paid to the producers was one that would be lawful upon a like transaction within the state." *Id.* The plaintiff in *Baldwin* was a New York milk dealer that purchased its milk from a Vermont creamery, which, in turn, purchased its milk from producers on neighboring Vermont farms. *Id.* at 518. While the only sale that was prohibited by the New York act was the sale between the dealer and his in-state buyer, the Supreme Court found that the act *effectively* regulated the out-of-state sale involving the Vermont producers. Pursuant to "the established doctrine . . . that a state may not, in any form or under any guise, directly burden the prosecution of interstate business," *id.* at 522 (quoting *Int'l Text-Book Co. v. Pigg*, 217 U.S. 91, 112 (1910)), the Court struck down the New York Act, reasoning that "New York has no power to project its legislation into Vermont by regulating the price to be paid in that state for milk acquired there." *Id.* at 521.

Like the statute at issue 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 be used to 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.[13] The *Baldwin* Court found this type of regulation – which uses an in-state hook to affect out-of-state conduct – to be an impermissible exercise of state power in violation of the Interstate Commerce Clause. *See also Brown-Forman*, 476 U.S. at 580 ("The mere fact that the effects of New York's ABC Law are triggered only by sales of liquor within the State of New York therefore does not validate the law if it regulates the out-of-state transactions of distillers who sell in-state."); *Healy*, 491 U.S. at 336 ("[T]he 'Commerce Clause . . . precludes the application of a state statute to commerce that takes place wholly outside the State's borders, whether or not the commerce has effects within the State . . . .'" (quoting *Edgar v. MITE Corp.*, 457 U.S. 624, 642-43 (1982) (plurality opinion))).

While the District argues that "[t]he Act does not control any out-of-District transaction," Defs.' Opp'n at 24, it is fanciful, at best, to see how, as applied to plaintiffs' members, the D.C. Act regulates anything but such transactions. Indeed, by specifically excluding "point of sale retail seller[s]" in the District from its reach, the only party that can be held liable under the D.C. Act is a "drug manufacturer or licensee thereof" for the sale of a patented prescription drug "that results in" a subsequent sale in the District for "an excessive price." *See* D.C. Act § 28-4553. Because all of plaintiffs' members who are manufacturers of patented prescription drugs are found out of state, and because all of the

[13] Because this is an as-applied challenge, we address only those upstream sales that involve out-of-state manufacturers like Plaintiffs' members.

wholesalers to whom they sell their products are also found out of state,[14] it is impossible to contend that this particular application of the D.C. Act does not effect an impermissible extraterritorial reach. Thus, under this factual scenario, there are absolutely no in-state transactions that the Act directly controls.

Because the Supreme Court has recognized that "[t]he critical inquiry is whether the practical effect of the regulation is to control conduct beyond the boundaries of the State," *Healy*, 491 U.S. at 336 (citing *Brown-Forman*, 476 U.S. at 579); *see also Brown-Forman*, 476 U.S. at 583 ("That the ABC Law is addressed only to sales of liquor in New York is irrelevant if the 'practical effect' of the law is to control liquor prices in other States." (citation omitted)), there is no question that the D.C. Act was intended to and will control out-of-state conduct. Plaintiffs' member manufacturers will not "remain free to conduct commerce on their own terms elsewhere, without either scrutiny or control by the District," Defs.' Opp'n at 23, because of the potential liability they will face in the District. Such a statutory scheme "has the practical effect of establishing 'a scale of prices for use in other states,'" *Healy*, 491 U.S. at 336 (quoting *Baldwin*, 294 U.S. at 528), which, as the District itself admits, a state cannot do. *See* Defs.' Opp'n at 25.

Moreover, as recognized by the Supreme Court in *Healy*, "the practical effect of the [challenged] statute must be evaluated not only by considering the consequences of the

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[14] In Plaintiffs' as-applied Commerce Clause challenge, this Court only addresses the constitutionality of those transactions that occur entirely out of state between out-of-state manufacturers, like Plaintiffs' members, and out-of-state entities, such as wholesalers. As previously stated, *see supra* note 10, this Court's analysis does not reach transactions between out-of-state manufacturers and entities – such as hospitals – located in the District.

statute itself, but also by considering how the challenged statute may interact with the legitimate regulatory regimes of other States and what effect would arise if not one, but many or every, State adopted similar legislation." 491 U.S. at 336. Although no other state has adopted a statute like the D.C. Act to date, 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. For example, similar legislation throughout the country would undoubtedly result in an artificial race between legislatures to set the lowest percentage above the foreign wholesale prices in the four designated countries as the base for a prima facie case. Such races to the bottom of the marketplace can be as dangerous to the interstate market as any other type of market failure, such as a monopoly or price-tying measures. *See Nat'l Ass'n of Home Builders v. Babbitt*, 130 F.3d 1041, 1049 (D.C. Cir. 1997) (characterizing a "race to the bottom" as having a "substantial harmful effect on interstate commerce").

Finally, the District's reliance on its general police powers to regulate matters of legitimate local concern, even citing these powers as a source of legitimacy in the Act itself, *see* D.C. Act § 28-4551(2) ("The traditional police powers of the District of Columbia include protecting and promoting the health, safety, and welfare of its residents . . . ."), is to no avail in this situation. While the District clearly retains such police powers, creating a public health exception to the Commerce Clause, such as the one advanced here, would "eat up the rule under a guise of an exception." *Baldwin*, 294 U.S. at 523; *see also Dean Milk Co.*

v. City of Madison, 340 U.S. 349, 354 (1951) ("[The] view . . . that [an] ordinance is valid simply because it professes to be a health measure, would mean that the Commerce Clause of itself imposes no limitations on state action other than those laid down by the Due Process Clause, save for the rare instance where a state artlessly discloses an avowed purpose to discriminate against interstate goods."); *cf. Brown-Forman*, 476 U.S. at 584 (holding that even the "wide latitude" to regulate liquor sales expressly conferred upon states by the Twenty-first Amendment "did not entirely remove state regulation of alcohol from the reach of the Commerce Clause"). Simply stated, the District's reliance on its police powers cannot, alone, overcome the otherwise unconstitutional reach of the D.C. Act.[15]

Thus, for all of the above reasons, this Court finds that the D.C. Act, as applied to sales between out-of-state manufacturers – like plaintiffs' members – and other out-of-state

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[15] The District's reliance on *Pharmaceutical Research and Manufacturers of America v. Walsh*, 538 U.S. 644 (2003), does not change this Court's analysis.

In *Walsh*, the Supreme Court reviewed the First Circuit's decision in *Pharmaceutical Research and Manufacturers of America v. Concannon*, 249 F.3d 66 (1st Cir. 2001), which examined the constitutionality of Maine's prescription drug rebate program. The state rebate program is a supplement to the federal Medicaid program and is intended to achieve additional cost savings for covered citizens in Maine. *Walsh*, 538 U.S. at 650. Under the program, Maine is authorized to negotiate rebates directly with drug manufacturers. Those manufacturers that do not enter into a rebate agreement are subject to prior authorization requirements before their products are covered under the program. *Id.* Among plaintiffs' claims in *Walsh* was a Commerce Clause challenge to the program. The *Walsh* plaintiffs argued, *inter alia*, that the rebate requirement constituted an "impermissible extraterritorial regulation." *Id.* at 669. Agreeing with the First Circuit, the Supreme Court found that the rules announced in *Baldwin* and *Healy* did not apply because "the Maine Act does not regulate the price of any out-of-state transaction, either by its express terms or by its inevitable effect. Maine does not insist that manufacturers sell their drugs to a wholesaler for a certain price." *Id.* (quoting *Concannon*, 249 F.3d at 81-82). But here, as discussed above, this Court finds that the inevitable effect of the D.C. Act *is* to regulate the price of out-of-state transactions. And although the D.C. Act does not set an exact price for which out-of-state manufacturers, like plaintiffs' members, must sell their drugs to out-of-state wholesalers the Act nevertheless effectively forces manufacturers to sell at a price less than thirty percent more than the wholesale price for the same drug 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.

entities has 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.

VI. Foreign Commerce Clause

Plaintiffs' final claim is a facial challenge to the D.C. Act under the Foreign Commerce Clause. *See* Pls.' Reply at 16 & n.15. "A facial challenge to a legislative Act is, of course, the most difficult challenge to mount successfully, since the challenger must establish that no set of circumstances exists under which the Act would be valid." *United States v. Salerno*, 481 U.S. 739, 745 (1987); *see also Amfac Resorts v. U.S. Dep't of Interior*, 282 F.3d 818, 826 (D.C. Cir. 2002) (noting that this Circuit has repeatedly "invoked *Salerno*'s no-set-of-circumstances test to reject facial constitutional challenges"), *cert. granted on other grounds sub nom. Nat'l Park Hospitality Ass'n v. Dep't of Interior*, 537 U.S. 1018 (2002); *S.D. Myers, Inc. v. City & County of San Francisco*, 253 F.3d 461, 467 (9th Cir. 2001) (applying *Salerno* to a Commerce Clause challenge and holding that the plaintiff "must establish that no set of circumstances exists under which the [challenged ordinance] would be valid" (internal quotation marks omitted)). Thus, in order to be successful in its facial challenge, plaintiffs have to prove that every conceivable application of the D.C. Act violates the Foreign Commerce Clause. By their own concession, however, it does not.[16]

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[16] *See* Pls.' Mem. of P. & A. with Respect to the Issue of Standing at 16-17 ("Section 28-4554 simply provides one means of pursuing a claim; it does not require plaintiffs to proceed in that manner, and it says nothing to confer amnesty upon manufacturers who would otherwise be liable under §28-4553."); *see also id.* at 17 n.18 ("If the prima facie case were the sole means of establishing liability, then manufacturers that do not sell drugs in any of the four benchmark foreign countries would be totally unregulated and no price controls would apply to those drugs, no matter how high the price in D.C. . . . [T]he statute's use of the phrase '[w]here a prima facie case of excessive pricing is shown' to introduce

The only portion of the D.C. Act that implicates the pricing of pharmaceutical sales abroad is Section 4554(a), which sets forth a formulaic approach to establishing a prima facie case of excessive pricing by comparing the domestic wholesale price of a drug with its wholesale price in one of four specified foreign countries. As stated earlier, and conceded by plaintiffs, Section 4554(a) is an *optional* approach to establishing a prima facie case that is provided to each "affected party." It is *not* an exclusive approach to establishing a prima facie case. Thus, to the extent that future plaintiffs are able to establish a prima facie case to the satisfaction of a Superior Court judge 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. As such, plaintiffs facial challenge to the D.C. Act under that clause must be dismissed.

CONCLUSION

For the foregoing reasons, the Court GRANTS plaintiffs' claims for declaratory and injunctive relief under the Supremacy and Interstate Commerce Clauses. An appropriate Order will issue with this Memorandum Opinion.

RICHARD J. LEON
United States District Judge

the burden-shifting framework in § 28-4554(b) further demonstrates that the prima facie case need not come into play in all lawsuits brought under the Act. The logical implication of that language is that where a prima facie case has *not* been shown, the traditional allocation of burdens will govern the lawsuit, and the plaintiff will simply have to establish the excessiveness of the challenged prices by some means other than the statutory prima facie case.").