IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

BIOTECHNOLOGY INDUSTRY ORGANIZATION
1225 Eye Street NW
Suite 400
Washington, DC 20005,

Plaintiff,

v.

THE DISTRICT OF COLUMBIA
1350 Pennsylvania Avenue, N.W.
Washington, D.C. 20004,

ANTHONY WILLIAMS,
in his official capacity as Mayor of the District of Columbia,
1350 Pennsylvania Avenue, N.W.
Suite 600
Washington, D.C. 20004,

OFFICE OF THE ATTORNEY GENERAL OF THE DISTRICT OF COLUMBIA
1350 Pennsylvania Avenue, N.W
Suite 409
Washington, D.C. 20004,

and

ROBERT J. SPAGNOLETTI,
in his official capacity as the Attorney General of the District of Columbia
1350 Pennsylvania Avenue, N.W.
Suite 407
Washington, D.C. 20004,

Defendants.

Civil Action No. _____

COMPLAINT

Plaintiff Biotechnology Industry Organization ("BIO") complains and alleges as follows:

INTRODUCTION

1. This lawsuit (along with a related suit filed by the Pharmaceutical Research and Manufacturers of America[1]) seeks to have this Court declare invalid, and enjoin the District of Columbia from enforcing, the Prescription Drug Excessive Pricing Act of 2005 ("the Act"). The Act has the stated purpose of reducing assertedly "excessive" prices for patented prescription drugs in the District. *See* Act § 2 (to be codified at D.C. Code § 28-4551). It would do so, however, by regulating companies and transactions wholly outside of the District of Columbia, and by affecting interstate and foreign commerce. Further, it would do all of this in ways that conflict directly with the federal statutory framework for encouraging investment in innovative and lifesaving technologies.

2. Under the Act, drug manufacturers and their licensees (but not point of sale retailers) are prohibited from "sell[ing] or supply[ing] for sale or impos[ing] minimum resale requirements for a patented prescription drug that results in the prescription drug being sold in the District for an excessive price." *See* Act § 2 (D.C. Code § 28-4553). The Act authorizes the District, as well as "any person directly or indirectly affected by excessive prices of patented prescription drugs," to bring suit for excessive pricing. *See* Act § 2 (D.C. Code § 28-4552(1), -4555). A prima facie case of excessive pricing is established by showing that the drug's wholesale price is more than 30% greater than the comparable price in any of four foreign countries.

[1] *See Pharmaceutical Research & Mfrs. of Am. v. District of Columbia*, No. 05-cv-02015-RJL (filed Oct. 12, 2005). That case and this one are related cases for purposes of Local Civil Rule 40.5, and a Notice of Designation of Related Civil Cases is being filed with this Complaint.

See Act § 2 (D.C. Code § 28-4554(a). It is then left to the defendant to rebut this prima facie case by showing that the drug is not excessively priced based on factors such as the cost of invention, global sales, and the ability of D.C. residents to pay the price in question. *See* Act § 2 (D.C. Code § 28-4554(b)).

3. The Act is particularly objectionable because it extends the District's reach into numerous other states and countries. It contains no geographical limitation on its scope. On the contrary, it purports to regulate every sale of patented prescription drugs that merely *results* in excessive prices in the District. A California manufacturer that sells a drug to a wholesaler in Illinois could apparently be sued under the D.C. law—and subjected to injunctive relief and treble damages, among other things—if the drug were ultimately sold in the District at a price that is deemed "excessive." Indeed, the Act all but guarantees that it will reach *only* parties and conduct outside the District. It specifically excludes "point of sale retail seller[s]." *See* Act § 2 (D.C. Code § 28-4553). It thereby limits its reach to pharmaceutical manufacturers, specialty pharmaceutical distributors, and wholesalers—the vast majority of which are not citizens of the District.

4. The extraterritorial scope and reach of the Act are not limited to the United States. Rather, the Act would link prescription-drug prices in the District to prices in four foreign countries whose governments strictly regulate drug prices. As a legal matter, this linkage would cause pharmaceutical manufacturers to take D.C. pricing effects into account when setting foreign sales and pricing policies. This effect on foreign commerce is flatly impermissible. As a practical matter, moreover, the Act would import a system of price controls that limits the amount of research and development investment a manufacturer (and potential investors) can recoup and potentially reinvest in future innovations. While the federal patent laws encourage

innovation by offering a market-based return, the price cap imposed by the D.C. Act prevents market-based returns. This aspect of the statute conflicts directly with federal law, and therefore causes further infirmity.

5. The last century has seen unprecedented improvements in public health, much of which has resulted from technological advances in the field of medicine. The continued improvement of public health, however, depends on the ongoing development of new and more effective treatments. The United States Congress has repeatedly recognized the critical need for robust medical research. Accordingly, and consistent with the Patent Clause of the United States Constitution, Congress has enacted and refined a national policy that creates incentives for investment in this area—specifically, an intellectual property regime to reward innovators.

6. This system maintains a careful balance. It encourages experimentation and innovation by granting an inventor the right to exclude others from practicing his or her patented invention for a term of years, but when that period ends, certain patent protections fall away. Recognizing the unique importance of medical innovation, Congress established a complementary system of incentives for research and innovation in that arena. *See, e.g.*, Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585, codified at 21 U.S.C. §§ 355, 360cc and 35 U.S.C. §§156, 271, 282; Food and Drug Modernization Act of 1997, Pub. L. No. 105-115, 11 Stat. 2296, codified at 21 U.S.C. § 355a; Orphan Drug Act, Pub. L. No. 97-414, codified at 21 U.S.C. § 360aa-360dd. The result of the underlying patent system, coupled with these additional incentives in the medical arena, has been large-scale investment by the national capital markets, whose participants undertake the risk of investing in medical innovation because the congressional framework seeks to ensure market-based returns. Nevertheless, the thirteen members of the District of Columbia City Council, and the Mayor of

the District, have determined that the mechanisms for innovation instituted by federal law are unsatisfactory, and now seek to recalibrate the balance established by Congress. This, the Supremacy Clause of the United States Constitution flatly forbids.

7. Because the Act regulates entities and conduct wholly outside the District, it violates the Commerce Clause of the United States Constitution. Art. I, § 8, cl. 3.

8. Because the Act infringes upon Congress's exclusive power to regulate commerce with foreign nations, it violates the Foreign Commerce Clause. U.S. Const. Art. I, § 8, cl. 3.

9. Because the Act upsets the congressionally established system of intellectual property generally, and medical intellectual property in particular, it is preempted by federal law, and violates the Supremacy Clause of the United States Constitution. U.S. Const. Art. VI, cl. 2.

JURISDICTION AND VENUE

10. The claims asserted in this Complaint arise under Article I, § 8 of the United States Constitution (the Commerce Clause); Article VI, cl. 2 of the United States Constitution (the Supremacy Clause); and 42 U.S.C. § 1983. Accordingly, this Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1331.

11. This Court may issue a declaratory judgment and "further necessary or proper relief" under 28 U.S.C. §§ 2201-2202.

12. Venue in this district is appropriate, pursuant to 28 U.S.C. § 1391(b).

THE PARTIES

13. BIO is the world's largest biotechnology organization, providing advocacy, business development, and communications services for more than 1,100 members across the United States and in 31 other nations. Corporate members span a continuum ranging from emerging companies in the process of developing their first therapy, to larger companies with multiple therapies already on the market. In addition, BIO represents state and regional biotechnology associations, academic centers, and service providers to the industry, such as legal and financial firms. The biotechnology industry has more than 200 biotech therapies and vaccines on the market, and hundreds of millions of people world-wide have benefited from these therapies.

14. The District of Columbia is a municipal corporation, which was established by Congress. *See* Act of February 21, 1871, ch. 62, 16 Stat. 419, 1. Pursuant to the Act, the District may bring suit against drug manufacturers (and their licensees) and seek civil penalties, fines, treble damages, injunctive relief, and fees and costs. *See* Act § 2 (D.C. Code § 28-4555(a), (b)).

15. Defendant Anthony A. Williams is sued in his official capacity as Mayor of the District of Columbia. He is authorized by statute to "take care that the laws [of the District] be faithfully executed," D.C. Code § 1-301.76, and the Office of the Attorney General of the District of Columbia operates "under the direction of the Mayor," *id.* § 1-301.111.

16. Defendant Office of the Attorney General of the District of Columbia, has "charge and conduct of all law business of the ... District, and all suits instituted by and against the government thereof," *id.*, and so will be responsible for bringing actions on behalf of the Dis-

trict of Columbia under the Act, *see* Act § 2 (D.C. Code § 28-4555(a)). Robert J. Spagnoletti is sued in his official capacity as the Attorney General.

BACKGROUND

Biotechnology Provides Profound Benefits and Offers Untold Future Promise to Society

17. Biotechnology is critical to the future of world healthcare, and the United States leads the world in biotechnology research and development. More than half of the investment in biomedical research and development made in public companies in G-7 countries occurs in the United States. Ernst & Young, *Beyond Borders: Global Technology Report 2005* 11 (2005). It is beyond question that the discrepancy in investment levels between the United States and its peer countries results from the free-market pricing system that prevails in the United States. In the United States, investors receive a market-based return on their investment, which is limited by the market value of the product. Free markets spur investment in discovery, which, in turn, benefits the public in the form of innovations that lead to valuable new treatments and cures for diseases, and therefore longer, healthier lives. In a jurisdiction that employs price caps on prescription drugs, by contrast, the potential return on investment is sharply limited.

18. Nevertheless, the District of Columbia seeks to import the price control regimes that have stymied biotechnological investment and development abroad. To understand the potential negative impact of this decision, it is first necessary to understand the importance of biotechnological innovation, and the nature of the market in which biotechnology companies operate.

19. Biotechnology is the use of cellular and biomolecular processes to solve problems or make useful products. Its application to address serious healthcare issues is well

recognized. The techniques of biotechnology enable the production—in living systems—of large, complex and sensitive therapeutic "macromolecules" that cannot be chemically synthesized, and that typically must be delivered by injection rather than as a traditional pill or gelcap. Healthcare biotechnology companies use the advances of biotechnology—such as new understandings of the structure and functioning of the human genome—to streamline and improve upon the discovery and development of traditional pharmaceuticals. Medical applications for biotechnology are numerous and growing exponentially. In the last twenty years, biotechnology research has yielded treatments for osteoporosis, heart attack, stroke, hemophilia, HIV/AIDS, chronic renal failure, multiple sclerosis, hepatitis, arthritis, anemia, pneumonia, infertility, attention deficit hyperactivity disorder, migraine, diabetes, and multiple forms of cancer. "[N]o new area of science and technology holds greater promise or potential than biotechnology." U.S. Dep't of Commerce, *A Survey of the Use of Biotechnology in U.S. Industry* vii (Oct. 2003).

20. In the next five to ten years, biotechnologies (mostly developed in the United States) could vastly improve health care in the developing world. Abdallah S. Daar *et al.*, *Top Ten Biotechnologies for Improving Health in Developing Countries*, 32 Nature Genetics 229 (Oct. 2002). Advances likely will occur, for instance, with regard to vaccination, sanitation techniques, and diagnosing infectious diseases. *Id.* "The diagnosis, prevention and, to some extent, management of common inherited diseases caused by a single defective gene are well advanced, and it is likely that, within the next few years, new diagnostic tools, vaccines, and therapeutic agents will be available for communicable diseases." World Health Organization, *Genomics and World Health: Report of the Advisory Committee on Health Research*, EB112/4, at 2 (April 2003). Thus, the benefits of biotechnology are not limited to wealthy, industrialized nations.

Impairing the ability of biotechnology companies to discover and deliver new therapies and new hope will have a profound impact on developing nations that anxiously await them.

Future Biotechnological Innovation Requires Investment in Research and Development

21. Despite biotechnology's remarkable breakthroughs, it remains an emerging field. Its further growth depends entirely on a firm commitment to invest in research and development. Indeed, "[t]he biotechnology industry is the most research and development-intensive and capital-focused industry in the world." NIH: Moving Research from the Bench to the Bedside: Hearings Before the Subcomm. on Health of the H. Comm. on Energy and Commerce, 108th Cong. 47 (2003) (testimony of Phyllis Gardner, M.D.). In 2004, global investment in biotechnology research and development exceeded $20.8 billion. Ernst & Young, *supra*, at 11. This constitutes a massive research and development expenditure of more than $113,632 per industry employee. *Id.* In 2001, investment in biotechnology research constituted 10% of research and development investment in the United States. Department of Commerce, *supra*, at xii. "The vast majority of biotech companies spend more than 50% of their operating expenses on research and development." NIH: Moving Research from the Bench to the Bedside, *supra*, at 49.

22. Despite the high costs of biotechnology research and development, most biotechnology companies are small ventures with little or no operating income to meet these costs. More than 85% of BIO members engaged in the research, development, and manufacture of biopharmaceuticals have fewer than 500 employees. *See* The Importance of the Biotechnology Industry and Venture Capital Support in Innovation: Hearings Before the Subcomm. on Rural Enterprises, Agriculture and Technology of the H. Comm. on Small Business, 109th Cong. (2005) (statement of the Biotechnology Industry Organization) (publication pending). In 2004,

the industry suffered a net loss of more than $5.3 billion. Ernst & Young, *supra*, at 11. As of 2005, of the over 1,444 biotechnology companies in the United States, *see* Ernst & Young, *supra*, at 11, a mere 125 had biotechnology therapies on the market, *information available through* http://www.bioworld.com (last visited Oct. 26, 2005).

23. These small, emerging companies must turn to private investors for capital to fund their time-, money-, and labor-intensive research. Currently, a full 98% of research and development investment in biotechnology comes from the private sector. NIH: Moving Research from the Bench to the Bedside, *supra*, at 49. The continued support of the private sector, however, is far from guaranteed, due to the highly speculative nature of biopharmaceutical therapy development.

High Risk Biotechnology Investments Require Commensurate Returns

24. The investment that a company makes to develop even a single therapy is astonishing. The average cost of developing a therapy exceeds $800 million, and development can take up to fourteen years. Tufts Center for the Study of Drug Development, News Release: Tufts Center for the Study of Drug Development Pegs Cost of a New Prescription Medicine at $802 Million (Nov. 30, 2001), at http://csdd.tufts.edu/NewsEvents/RecentNews.asp?newsid=6 (last visited Oct. 20, 2005). The chances that a biopharmaceutical will achieve FDA approval are approximately one in 5,000. Tommy Thompson, Secretary, Department of Health and Human Services, Address at the Milken Institute Global Conference (Apr. 26, 2004), *available at* http://www.hhs.gov/news/speech/2004/040426.html. Of those therapies that do reach market, a mere one-third cover their cost of development, much less turn a significant profit. John V. Duca & Mine K. Yücel, *An Overview of Science and Cents. Exploring the Economics of Biotechnology*, Federal Reserve Bank of Dallas Economic and Financial Policy Review, at 4 (2002).

25. In fact, biotechnology is such a high risk field of investment that biotechnology companies are able to secure less than one-half of their total financing through debt offerings. G. Steven Burrill, *supra*, at 532. Much of biotechnology investment therefore comes from venture capitalists and initial public offerings. Of the 50 United States and European biotechnology companies that went public in 2003 and 2004, the vast majority were funded in large part by venture capital. Andreas Wicki, *Global Venture Capital Developments*, in Beyond Borders: Global Biotechnology Report 2005, at 9. Many biotechnology ventures face such serious need for early investment that, after a first round of financing, the new investors own a majority stake in the enterprise.

26. In short, the majority of biotechnology companies are small, emerging companies with few employees, no therapies on the market, and no operating income. Their primary asset is a patented or patentable invention. They must find investors willing to risk hundreds of millions of dollars on a less than 0.02% chance of the therapy reaching market and turning a profit. The company must not only convince investors that its long-shot invention will pay off, but that the company is a better investment than the countless alternatives. The challenge is intensified by the conventional wisdom that investors "are interested in companies that either have products or have well-articulated business plans for bringing products to market in relatively short time horizons." Ernst & Young, *supra*, at 30. Indeed, in the past six years, the percentage of capital raised in early round financing by companies without therapies on the market dropped from approximately 18% to less than 5%. *Id.* at 29.

27. Emerging companies have only a single enticement to offer investors: the prospect that, if the therapy reaches market and fills a need in the healthcare field, it will earn market-based returns.

28. The D.C. Act will deprive emerging biotechnology companies of their ability to attract crucial financing by seriously impacting their single enticement—the potential for market-based returns if the product is a success. By importing the price control regimes of foreign nations, the D.C. Act prohibits companies from asking potential buyers to pay the true market value of a therapy that has surmounted nearly immeasurable odds to reach the marketplace. There is no question that limiting the return on investment in biopharmaceuticals presents potentially insurmountable challenges for companies trying to obtain financing.

Price Control Regimes Significantly Impact Worldwide Investment in Biotechnology

29. Research has shown that fluctuations in profit variables and key marginal costs significantly affect investment patterns. Jason G. Cummins, et al., *Investment Behavior, Observable Expectations, and Internal Funds*, Board of Governors of the Federal Reserve System, Finance and Economics Discussion Papers 99/27 (1999).

30. In the field of therapy development specifically, studies show that price control regimes stymie innovation and negatively impact healthcare. One analysis suggests that, were certain foreign countries to adopt the free-market pricing system that prevails in the United States, investment in research and development would increase by $17-22 billion. Charles-Andre Brouwers, et al., *Adverse Consequences of OECD Government Interventions in Pharmaceutical Markets on the U.S. Economy and Consumer* (July 2004). Other studies have demonstrated that the resulting revenue increase would more than double the number of new pharmaceutical compounds available. Daron Acemoglu & Joshua Linn, *Market Size in Innovation: Theory and Evidence from the Pharmaceutical Industry* (NBER Working Paper 10038) (2003).

31. Not surprisingly, then, investment in biotechnology in the United States has far outpaced European investment in biotech. In 2004, total equity financing in biotechnology in the United States was slightly less than $17 billion. Ernst & Young, *supra*, at 11. In Europe, the total was $3.4 billion, a mere 20% of the United States investment. *Id.*

32. The historical trends in price control countries are equally stark. Between 1992 and 2002, investment in drug research and development rose by 8% annually in Europe, as compared to 11% annual growth in the United States. Jim Gilbert & Paul Rosenberg, *Addressing the Innovation Divide: Imbalanced Innovation*, presented at the World Economic Forum Annual Meeting, at 3 (2004). The discrepancy in investment resulted in a decrease in innovation. Between 1993 and 1997, 81 new therapies were introduced in Europe, while only 48 were launched in the United States. *Id.* Over the next four years, the number of therapies introduced in Europe dropped by more than 45%, while the number of therapies introduced in the United States more than doubled. *Id.* In Germany, one of the countries chosen as a model by the District of Columbia, drug price controls have resulted in a net loss of $3 billion to the economy. *Id.* at 3-4. Additionally, as a percentage of health care costs, the United States spends less money on drugs than do either Germany or the United Kingdom. Roger Edwards, et al., Examining the Relationship Between Market-Based Pricing and Bio-Pharmaceutical Innovation 6 (2002), *available at* http://www.ftc.gov/os/comments/intelpropertycomments/littlearthurd2.pdf.

33. If the D.C. Act were to stand, there would be nothing to stop the same thing from happening in the United States. Analysts have repeatedly warned of the danger that proposed price control regimes would present to the United States' continued global leadership in the field of therapy development. The biotechnology "industry relies heavily on private investments to fund research, and investors are clearly uncomfortable with the prospect of price

controls, direct or indirect. Decrease[s] in investor confidence can only result in a decrease in investment dollars, thereby placing critical research at risk. In addition, biopharmaceutical price controls will inevitably, and perhaps irreparably, damage the financial health of these dynamic companies and the hundreds of thousands of citizens they employ." Letter from Alfred R. Berkeley III, President, NASDAQ, to Hon. Dennis J. Hastert, Speaker, U.S. House of Rep. (on file with BIO) (May 16, 2000).

34. Moreover, as an economic matter, risk and return are appropriately aligned in drug development investment. Edwards, et al., *supra*, at 12. In fact, drug development offers significantly lower rates of return over the cost of investment than do other research and development-intensive industries such as computer networking. *Id.* at 15. Further limiting potential return on drug development investments will put biotechnology companies at a serious competitive disadvantage in a market teeming with less risky opportunities for investors.

35. Further, the free market is itself a price control mechanism. Rather than limiting prices through government fiat, as the District now attempts to do, Congress has relied on free market competition to determine the value of biotechnology treatments. For the reasons discussed above, this reliance on free markets has made the United States pharmaceutical industry the envy of, and the supplier of newer and better therapies to, the rest of the world. Moreover, many approaches are available to assure access to affordable pharmaceuticals, other than the adoption of price controls that extinguish the capital markets that drive the United States to be the world's leader in biomedical innovation. BIO has sought to discuss these alternatives with the government of the District of Columbia. In fact, the District passed legislation in 2004 that authorizes creation of a discount prescription drug program, but has failed to implement the act. AccessRx Act of 2004, D.C. Code § 48-831.01 (2005).

36. Of fundamental importance in this system is the ability of healthcare innovators to pass the benefits of their research to patients in the United States and around the world. It is for their benefit that Congress has chosen to rely on free-market pricing to spur experimentation and discovery. It is not merely the economies of other nations that have suffered as a result of their price control policies; the impact of these policies is felt most strongly by the people who lack the critical therapies that pharmaceutical research in general, and biopharmaceutical research in particular, can offer.

The D.C. Act Violates the U.S. Constitution

37. The D.C. City Council has sought to impose itself on the national marketplace by regulating the price of patented pharmaceutical therapies—and *only* those therapies that are patented—and to reach outside of the borders of the District and the United States to do so. This is flatly impermissible, for at least three reasons.

38. The Commerce Clause of the United States Constitution grants Congress the exclusive right to "[r]egulate Commerce among ... the several States," U.S. Const. art. I, § 8, cl. 3, and states (including the District) are thereby forbidden to regulate conduct wholly outside their borders. This Act, however, regulates interstate commerce directly. It creates a cause of action against manufacturers and their licensees—the vast majority of which, in the case of BIO members and their customers, are not citizens of the District. Every BIO member engaged in biopharmaceutical research and development is located outside of the District, and those companies sell the vast majority of their therapies to wholesalers, specialty pharmaceutical distributors, and retail chains that are located outside the District. However, the Act places these transactions within the reach of D.C. law, because a manufacturer would be liable whenever a therapy may

make its way to the District and be sold at an "excessive" price. Ironically, by excluding point of sale retailers, the Act exempts the vast majority of transactions that even touch the District.

39. The Act likewise usurps Congress's exclusive right to regulate foreign commerce. The United States Constitution grants Congress the exclusive right to "[t]o regulate Commerce with foreign Nations." U.S. Const. art. I, § 8, cl. 3. The D.C. Act infringes upon this exclusive right. Under the Act, domestic manufacturers that sell their therapies both domestically and abroad might be forced to alter foreign pricing and sales in a manner that anticipates their impact on domestic prices. The D.C. Act establishes this linkage. This effect will be magnified if the D.C. Act is upheld and additional states follow its lead. It is not within the province of the D.C. Council to regulate in this fashion. Furthermore, the Act will cause domestic courts to pass judgment on foreign pricing schemes, which will interfere with the foreign relations power.

40. Finally, the District of Columbia's decision to limit the prices of patented pharmaceutical therapies frustrates the patent system enacted by Congress. Pursuant to Congress's constitutional power to grant authors and inventors exclusive rights to their creations for limited times "to promote the Progress of Science and useful Arts," U.S. Const. art. I, § 8, cl. 8, it has created—and repeatedly refined—the patent system. *See* 35 U.S.C. § 100 *et seq.* Under this regime, inventors have the exclusive right to market their inventions for a limited time, and to capture a market-based royalty.

41. Congress has repeatedly demonstrated its belief that the patent regime is crucial to innovation and progress in the field of medical technology. Moreover, Congress constantly reviews and refines this area of law to maintain the best possible balance for the public

between rewarding innovation and making new treatments widely available to the public. For instance, since the present term of exclusivity runs from the filing date, Congress was concerned about delays in granting a patent (and thus delays in enforcement) caused by the U.S. Patent and Trademark Office. It therefore enacted a statute that gives the patentee an additional term equal to such delays under certain conditions. 35 U.S.C. § 154(b) (2000). Congress has been especially concerned about balancing risk and return in the medical field, creating an additional period of exclusive rights to mitigate, in appropriate circumstances, the length of the rigorous FDA review and approval process. *Id.* § 156(a) (2000) (codification of portions of the 1984 Hatch-Waxman Act).

42. This period of market exclusivity creates incentives for innovators to develop their ideas, and for investors to take risks on commercializing those ideas. "The economic philosophy behind the clause empowering Congress to grant patents and copyrights is the conviction that encouragement of individual effort by personal gain is the best way to advance public welfare through the talents of authors and inventors in 'Science and useful Arts.' Sacrificial days devoted to such creative activities deserve rewards commensurate with the services rendered." *Mazer v. Stein*, 347 U.S. 201, 219 (1954). In short, American intellectual property "law *celebrates* the profit motive," and "recogniz[es] that the incentive to profit … will redound to the public benefit by resulting in the proliferation of knowledge." *Eldred v. Ashcroft*, 537 U.S. 186, 212 n.18 (2003) (quoting *American Geophysical Union v. Texaco, Inc.*, 802 F. Supp. 1, 27 (S.D.N.Y. 1992)).

COUNT I
(Declaratory/Injunctive Relief – Violation of the Dormant Commerce Clause of Art. I, § 8, cl. 3 of the U.S. Constitution)

43. BIO realleges and incorporates by reference the preceding paragraphs of this Complaint as if fully set forth herein.

44. Pursuant to the Commerce Clause of the United States Constitution, "Congress … ha[s] Power … To regulate Commerce … among the several States." *See* Art. I, § 8, cl. 3. This grant of power to the national Congress prohibits states (and the District of Columbia) from regulating interstate commerce. A state statute that "regulates conduct occurring wholly outside the state" violates the Commerce Clause, *Brown-Forman Distillers Corp. v. New York State Liquor Auth.*, 476 U.S. 573, 582 (1986) (quoting *United States Brewers Ass'n, Inc. v. Healey*, 692 F.2d 275, 279 (2d Cir. 1982)), as does a statute that seeks "'directly' to assert extra-territorial jurisdiction over persons or property," *Healy v. Beer Institute*, 491 U.S. 324, 336 n.13 (1989) (quoting *Edgar v. MITE Corp.*, 457 U.S. 624, 643 (1989)).

45. The D.C. Act violates the Commerce Clause. By its plain terms, it would regulate conduct that occurs wholly outside of the District, by directly asserting jurisdiction over companies and prescription therapies that are located outside of the District. Specifically, the Act makes it "unlawful for any drug manufacturer or licensee thereof … to sell or supply for sale … a patented prescription drug that results in the prescription drug being sold in the District for an excessive price." Act § 2 (D.C. Code 28-4553). The Act does not require that any aspect of the "sale or supply" take place in the District, nor that any party to the transaction reside in (or even be incorporated in) the District. Rather, the Act seeks to regulate *any* transaction that merely *results* in an "excessive price" in the District, regardless of where the transaction occurs.

46. No member of BIO engaged in the development of biopharmaceuticals is located in the District, nor does any have a warehouse in the District. The vast majority of sales by BIO members are to wholesalers, specialty pharmaceutical distributors, or large retail chains headquartered outside the District. Similarly, the vast majority of these buyers does not receive shipments from BIO members in warehouses in the District. By excluding retail (point of sale) transactions, the Act excludes the vast majority of transactions that necessarily occur in the District.

47. The Act regulates conduct occurring wholly outside the District and is void.

COUNT II
(Declaratory/Injunctive Relief – Violation of the Foreign Commerce Clause of Art. I, § 8, cl. 3 of the U.S. Constitution)

48. BIO realleges and incorporates by reference the preceding paragraphs of this Complaint as if fully set forth herein.

49. The Commerce Clause of the United States Constitution vests in Congress the power "[t]o regulate Commerce with foreign Nations." U.S. Const. Art. I, § 8, cl. 3. Foreign commerce has long been recognized as a matter of national concern. To ensure uniformity of action, the United States must act through a single, national government where foreign commerce is concerned. Accordingly, Congress's power over foreign commerce is exclusive, absolute and plenary, and "may not be limited, qualified, or impeded to any extent by state action." *Board of Trustees of Univ. of Ill. v. United States*, 289 U.S. 48, 56-57 (1933). Indeed, Congress's dominion over foreign commerce is even more sweeping than its power over interstate commerce.

50. The D.C. Act violates the Foreign Commerce Clause by linking the prices for patented prescription therapies in the District to therapy prices overseas. It does so by labeling as presumptively "excessive" any drug in the District whose wholesale price "is over 30% higher than the comparable price in" the United Kingdom, Germany, Canada or Australia. Act § 2 (D.C. Code §§ 28-4553, -4554(a)). This policy interferes with foreign commerce by affecting manufacturers' sales and pricing policies in foreign countries, and it is therefore constitutionally invalid.

51. Moreover, the D.C. Act interferes with the exclusive right of the federal government to conduct foreign affairs. Because drug prices in the foreign nations referenced by the Act are capped and negotiated by the governments of those countries, the Act places the D.C. government and the D.C. courts in the position of judging the reasonableness of foreign pricing, and the merits of foreign governments' decisions. This imprudent assumption of expansive authority usurps the federal government's exclusive authority to manage international relations.

COUNT III
(Declaratory/Injunctive Relief – Preemption by the Federal Patent Laws)

52. BIO realleges and incorporates by reference the preceding paragraphs of this Complaint as if fully set forth herein.

53. The United States Constitution provides that the laws of Congress are "the supreme Law of the Land." U.S. Const., art. VI, cl. 2. When Congress has chosen to exercise its constitutionally supplied powers, and state law interferes with that exercise, "[i]n every such case, the act of Congress . . . is supreme; and the law of the State, though enacted in the exercise of powers not controverted, must yield to it." *Gibbons v. Ogden*, 22 U.S. (9 Wheat.) 1, 211 (1824).

54. Congress has the constitutional authority to regulate intellectual property, *see* U.S. Const. art. I, sec. 8, cl. 8, and pursuant to that power, Congress has established an extensive system for the granting and maintenance of patents, *see* 35 U.S.C. § 1 *et seq*. Through this system, Congress has acted to bring uniformity to the patent arena through federal regulation. *Sears, Roebuck & Co. v. Stiffel Co.*, 376 U.S. 225, 231 n.7 (1964) ("The purpose of Congress to have national uniformity in patent and copyright laws can be inferred from such statutes as that which vests exclusive jurisdiction to hear patent and copyright cases in federal courts."); *see also Sony Corp. of Am. v. Universal Studios, Inc.*, 464 U.S. 417, 429 (1984) ("[I]t is Congress that has been assigned the task of defining the scope of the limited monopoly that should be granted to authors. . . in order to give the public appropriate access to their work product.").

55. Congressional regulation of patent law is particularly pervasive in the field of pharmaceuticals. In 1984, for instance, Congress enacted the Drug Price Competition and Patent Term Restoration Act, an intellectual property regime that applied exclusively to pharmaceuticals. Pub. L. No. 98-417, 98 Stat. 1585 (codified at 21 U.S.C. §§ 355, 360(cc) (2000), 35 U.S.C. §§ 156, 271(e) and 282(4) (2000)). Moreover, Congress long ago established a regulatory agency dedicated solely to overseeing the food and drug industry, recognizing the critical need for uniform national procedures in moving pharmaceuticals from the laboratory to the free market. 21 U.S.C. § 301 *et seq.*

56. The reason for this comprehensive legislative scheme is clear. Congress has concluded that giving innovators the exclusive right to sell their products at a free market rate for a prescribed term of years reaches the best balance between providing incentive to innovate and making innovations widely available to the public. In the pharmaceutical arena, Congress has worked assiduously to balance these competing values, with regulations concerning

development, marketing, and pricing of drugs. In short, a local price control statute undermines the system that Congress has established.

57. The D.C. Act "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress," and so is invalid under the Supremacy Clause. *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941). By setting a maximum price at which drugs can be sold—not only in the District, but anywhere, if the drug might ultimately reach the District—the Council announced its belief that the appropriate balance between incentives for innovation and availability of pharmaceuticals should be adjusted. The D.C. Act would lessen the incentive to innovate by capping the rewards that may be reaped. This is not the balance that Congress established, and this is not the D.C. Council's decision to make.

58. The D.C. Act is preempted by federal law and is therefore void.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff BIO prays:

A. For a declaration that the D.C. Act is invalid;

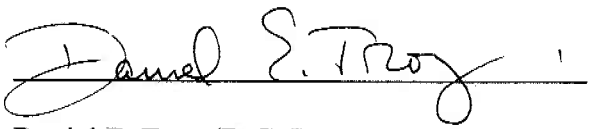
B. For a permanent injunction prohibiting the District of Columbia, the Mayor, and the Attorney General from bringing suit under the Act, or implementing or enforcing the Act in any way;

C. For such costs and reasonable attorneys' fees to which it might be entitled by law; and

D. For such other or further relief that this Court deems just and appropriate.

Dated: October 27, 2005

Respectfully submitted,



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