BIOTECHNOLOGY INDUSTRY ORGANIZATION V. DISTRICT OF COLUMBIA: A PREEMPTIVE STRIKE AGAINST STATE PRICE RESTRICTIONS ON PRESCRIPTION PHARMACEUTICALS

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I. INTRODUCTION

Truvada, a medication used to treat AIDS, costs nearly $900 or more for 30 tablets.[1] The same quantity of Abilify, a psychotropic used to treat schizophrenia, can cost over $500.[2] An Advair Diskus for long-term treatment of asthma costs $180.[3] A syringe of Enbrel, a medication to reduce the symptoms of rheumatoid arthritis, has a staggering price of more than $2,000.[4]

Given the startlingly high prices of patented pharmaceuticals, it comes as no surprise that state legislators have pushed to reduce the cost of brand name drugs for their constituents. A recent example of this type of legislation is the District of Columbia's Prescription Drug Excessive Pricing Act of 2005.[5] The Excessive Pricing Act made it illegal for District pharmacies to sell patented pharmaceuticals at an "excessive" price, as defined by statute.[6] On August 1, 2007, the Federal Circuit determined that the Excessive Pricing Act was preempted by federal patent law in *Biotechnology Industry Organization v. District of Columbia*.[7]

In *Biotechnology Industry Organization*, the Federal Circuit held that the Excessive Pricing Act stood as an obstacle to the

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[1] PharmacyChecker.com, Pricing & Ordering Comparisons, All Prices For: Truvada – Brand Version: 200-300mg, http://www.pharmacychecker.com/Pricing.asp?DrugName=Truvada&DrugId=59317&DrugStrengthId=116833 (last visited Apr. 1, 2009).

[2] PharmacyChecker.com, Pricing & Ordering Comparisons, All Prices For: Abilify – Brand Version: 30mg, http://www.pharmacychecker.com/Pricing.asp?DrugName=Abilify&DrugId=24894&DrugStrengthId=41747 (last visited Apr. 1, 2009).

[3] PharmacyChecker.com, Pricing & Ordering Comparisons, All Prices For: Advair Diskus – Brand VersionL 100/5 0, http://www.pharmacychecker.com/Pricing.asp?DrugName=Advair+Diskus&DrugId=18398&DrugStrengthId=96193 (last visited on Apr. 1, 2009).

[4] PharmacyChecker.com, Pricing & Ordering Comparisons, All Prices For: Enbrel – Brand Version: 25 mg, http://www.pharmacychecker.com/Pricing.asp?DrugName=Enbrel&DrugId=25308&DrugStrengthId=46852 (last visited on Apr. 1, 2009).

[5] Law of Dec. 10, 2005, tit. 28, ch. 45B, § 28-4551 to 4555, 2005 D.C. Laws ch. 45B, *invalidated by* Biotechnology Indus. Org. v. District of Columbia, 496 F.3d 1362 (Fed. Cir. 2007) (holding the Act to be preempted by federal law).

[6] D.C. CODE ANN. § 28-4554(a) (LexisNexis 2001 & Supp. Mar. 2008) ("A prima facie case of excessive pricing shall be established where the wholesale price of a patented prescription drug in the District is over 30% higher than the comparable price in any high income country in which the product is protected by patents . . . .").

[7] Biotechnology Indus. Org. v. District of Columbia, 496 F.3d 1362, 1365 (Fed. Cir. 2007).

balance of objectives established by Congress through the federal patent laws.[8] The issue addressed in this Note is whether state regulation of prescription drug prices is appropriately preempted by federal patent law.

Part II of this Note begins with an overview of patent law and policy as it relates to prescription pharmaceuticals. This part continues with a discussion of patent preemption doctrine and its relationship to various forms of state regulation, and finishes by explaining the Excessive Pricing Act and the Federal Circuit's preemption decision in *Biotechnology Industry Organization*. Part III analyzes problems with the *Biotechnology Industry Organization* decision and the difficult fit between the Excessive Pricing Act and the categorical preemption doctrines. It goes on to examine whether a general pharmaceutical price restriction could withstand preemption. Part IV concludes that despite the problems presented by the *Biotechnology Industry Organization* decision, it is likely that a general pharmaceutical price restriction would not be preempted by federal patent law.

II. BACKGROUND

a. Pharmaceutical Patent Protection

1. The Federal Patent Laws

"The federal patent system . . . embodies a carefully crafted bargain for encouraging the creation and disclosure of new, useful, and non-obvious advances in technology and design in return for the exclusive right to practice the invention for a period of years."[9] The Constitution of the United States empowers Congress "[t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."[10] Congress has acted upon this constitutional authority by enacting the federal patent laws, which are codified in Title 35 of the United States Code.[11] As a general enactment, Title 35 sets forth the requirements of patentability; affords

[8] *Id.* at 1374.

[9] Bonito Boats, Inc. v. Thunder Craft Boats, Inc., 489 U.S. 141, 150–51 (1989).

[10] U.S. CONST. art. I, § 8, cl. 8.

[11] 1 R. CARL MOY, MOY'S WALKER ON PATENTS § 2:3 (4th ed. 2007) (discussing how Title 35 exemplifies a general patent act by Congress).

patent holders the exclusive right to make, use, and sell a qualifying invention for a period of 20 years from the date of patent application; and delegates authority to the United States Patent and Trademark Office to administer the issuance of patents.[12]

2. The Hatch-Waxman Act

Prescription pharmaceuticals are a subject of special treatment in patent law. In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act, informally known as the Hatch-Waxman Act, to authorize the extension of patent terms for certain approved pharmaceuticals.[13] The Hatch-Waxman Act sought to "str[i]ke a balance between two competing policy interests: (1) inducing pioneering research and development of new drugs and (2) enabling competitors to bring low-cost, generic copies of those drugs to market."[14] Prior to the Hatch-Waxman Act, the pharmaceutical industry faced abbreviated effective patent terms due to the substantial gap in time between the issuance of a patent and FDA approval of the corresponding drug.[15] The Hatch-Waxman Act responded "by providing brand name drug manufacturers with limited extensions of their patent terms in order to restore a portion of the market exclusivity lost through the lengthy process of drug development and FDA approval."[16] The Act counterbalanced this benefit to brand name drug manufacturers by creating a patent infringement exception for experiments by generic drug manufacturers and shortening the FDA approval process for generic drugs.[17] The Hatch-Waxman Act reflects the unique significance of patent protection in the pharmaceutical industry and helps define the policies underlying patent protection for prescription drugs.

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[12] *See generally* 35 U.S.C. §§ 1–154 (2000) (explaining the requirements found in Title 35).

[13] Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended in scattered sections of 35 U.S.C.).

[14] Andrx Pharm., Inc. v. Biovail Corp., 276 F.3d 1368, 1371 (Fed. Cir. 2002).

[15] Richard J. Smith, *Hatch-Waxman 2003 – Patented v. Generic Drugs: Regulatory, Legislative, and Judicial Developments*, 20 SANTA CLARA COMPUTER & HIGH TECH. L.J. 695, 697 (2004).

[16] Allergan, Inc. v. Alcon Labs., Inc., 324 F.3d 1322, 1325 (Fed. Cir. 2003).

[17] *Id.*

3. Patent Policy and the Pharmaceutical Industry

Effective patent protection is essential to the research-intensive pharmaceutical industry.[18] Pharmaceutical innovation has been characterized as a "highly expensive and risky business."[19] There are four principal stages required to introduce a new pharmaceutical into the market: (1) discovery of new compounds, (2) preclinical testing in laboratories and animals, (3) clinical trials, and (4) FDA review.[20] The entire process requires an average of twelve to fifteen years to complete with estimated costs in excess of $802 million.[21] On average, only one out of every 10,000 compounds initially identified for development will actually receive FDA approval.[22] In addition, industry statistics indicate that only thirty percent of pharmaceuticals obtaining FDA approval succeed in recouping the average cost of research and development.[23]

Gerald J. Mossinghoff, a commentator for the pharmaceutical industry, stated that "[e]ffective patent protection at home and abroad is vitally important to the United States pharmaceutical industry."[24] According to Mossinghoff, the pharmaceutical industry's investment in research and development of new technology "depends greatly upon the extent to which foreign governments allow innovators to be rewarded for their

[18] *See* Evan Ackiron, *Patents for Critical Pharmaceuticals: The AZT Case*, 17 AM. J.L. & MED. 145, 145 (1991) (explaining that patent protection is used to promote scientific research and innovation).

[19] Theresa Beeby Lewis, Comment, *Patent Protection for the Pharmaceutical Industry: A Survey of the Patent Laws of Various Countries*, 30 INT'L L. 835, 842 (1996) (citing *Drug Pricing Before the S. Comm. on Governmental Affairs* (1994) (statement of Gerald J. Mossinghoff, President, Pharmaceutical Research and Manufacturers of America).

[20] Brief for The AIDS Institute as Amicus Curiae in Support of Plaintiffs-Appellees, Biotechnology Indus. Org. v. District of Columbia, 496 F.3d 1362 (2007) (No. 2006-1593), [hereinafter *AIDS Institute*] (citing U.S. GOV'T. ACCOUNTABILITY OFFICE, NEW DRUG DEVELOPMENT: SCIENCE, BUSINESS, REGULATORY AND INTELLECTUAL PROPERTY ISSUES CITED AS HAMPERING DRUG DEVELOPMENT EFFORTS 6 (Nov. 2006)[hereinafter *GOV'T ACCOUNTABILITY OFFICE*]).

[21] *See id.* at 6–7 (citing an average development period of fifteen years at an estimated cost of $802 million); *cf.* Lewis, *supra* note 19, at 842 ("It takes an average of twelve years to discover and develop new pharmaceuticals at an estimated cost of $359 million.").

[22] *AIDS Institute*, *supra* note 20, at 6 (citing U.S. GOV'T. ACCOUNTABILITY OFFICE, *supra* note 20, at 7).

[23] Lewis, *supra* note 19, at 842.

[24] Gerald J. Mossinghoff, *Research-Based Pharmaceutical Companies: The Need for Improved Patent Protection Worldwide*, 2 J.L. & TECH. 307, 307 (1987).

inventiveness, monetary investment, and intellectual labor."[25] From an industry perspective focused on the economic rewards of innovation, only effective patent protection can ensure the commitment of resources required for innovation.[26]

In contrast to industry concerns, proponents of a consumer-oriented perspective contend that "[t]he United States [sic] in the midst of a health care affordability crisis, driven in major part by the skyrocketing of prescription drug prices over the last decade."[27] Consumer statistics indicate that "[s]ince 1990, U.S. consumer spending for prescription drugs has increased over five-fold to $251.8 billion (2005), rising twice as fast as the rest of health spending and 4.5 times faster than the economy as a whole."[28] This increase in spending is partly attributable to the fact that the yearly increase in prescription drug prices has consistently exceeded twice the general inflation rate,[29] while the average price per prescription drug swelled from $9.50 in 1981 to $53.92 in 2004.[30]

During this period of rising drug prices, profit rates throughout the pharmaceutical industry were consistently much higher than

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[25] *Id.* ("For the private sector pharmaceutical industry, which has been the primary source of new therapies for the past four decades, there is little incentive to provide an ever-increasing commitment to research unless there are reasonable expectations of financial return.").

[26] *Id.*

[27] Brief for the National Legislative Association on Prescription Drug Prices et al. as Amici Curiae in Support of Defendants-Appellants, Biotechnology Indus. Org. v. District of Columbia, 496 F.3d 1362 (2006) (No. 2006-1593), 2006 WL 3846637 [herinafter *Association on Prescription Drug Prices*].

[28] *Id.* at 2 (citing KAISER FAMILY FOUND., PRESCRIPTION DRUG TRENDS FACT SHEET, 1 (June 2006), http://www.kff.org/rxdrugs/upload/3057-05.pdf (last visited Apr. 1, 2009); PAUL BROWN, U.S. PIRG EDUC. FUND, PAYING THE PRICE: THE HIGH COST OF PRESCRIPTION DRUGS FOR UNINSURED AMERICANS, 7 (Sept. 2006); Centers for Medicare & Medicaid Services, National Health Expenditures Aggregate Amounts and Average Annual Percentage Change, by Type of Expenditure: Selected Calendar Years 1960–2007, tbl.2, *available at* http://www.cms.hhs.gov/NationalHealthExpendData/downloads/tables.pdf; Alan Sager & Deborah Socolar, *Do Drug Makers Lose Money on Canadian Imports?*, Health Reform Program, Data Brief No. 6 (Apr. 15, 2004), *available at* http://sph.bu.edu/images/stories/scfiles/healthservices/health_reform/Canadian_importing_break_even_14_Apr04_FINAL.pdf).

[29] *Id.* (citing KAISER FAMILY FOUND., PRESCRIPTION DRUG TRENDS FACT SHEET, 1 (Oct. 2004), http://www.kff.org/rxdrugs/upload/Prescription-Drug-Trends-October-2004-UPDATE.pdf (last visited Apr. 1, 2009)).

[30] Alan Sager & Deborah Socolar, *Let Them Eat Coke? Cocaine and Heroin Become Cheaper While Prescription Drugs Become Costlier*, Health Reform Program, Data Brief No. 11 (Apr. 12, 2006), *available at* http://dcc2.bumc.bu.edu/hs/Let%20Them%20Eat%20Coke%2012Apr06%20with%20citations.pdf.

in other sectors.[31] For example, "[i]n 2002, the ten pharmaceutical companies on the Fortune 500 list made more profits than the other 490 businesses on the list combined."[32] In addition, pharmaceuticals that contain patented active ingredients "are typically priced about five times [higher than] would be set by competitive markets."[33] Consumer advocates argue that the unfettered ability of drug companies to increase the prices of patented products has created "a widening gap between the U.S. and other wealthy countries' prices for prescription drugs."[34]

b. Patent Preemption

The concept of preemption derives from the Supremacy Clause of the United States Constitution, which provides that "the Laws of the United States . . . shall be the supreme Law of the Land."[35] The United States Supreme Court has recognized three general ways in which federal law may preempt state law: express preemption, field preemption, and conflict preemption.[36] Express preemption occurs when state law is displaced by a command explicitly stated in the language of a statute.[37] Field preemption occurs when a "scheme of federal regulation [is] so pervasive as to make reasonable the inference that Congress left no room for the States to supplement it."[38] Finally, conflict preemption arises

[31] *Association on Prescription Drug Prices*, *supra* note 27, at 3 (citing NAT'L INST. FOR HEALTH CARE MGMT., PRESCRIPTION DRUGS AND INTELLECTUAL PROPERTY PROTECTION 3 (2000), *available at* http://www.nihcm.org/~nihcmor/pdf/prescription.pdf).

[32] *Id.* at 3–4 (citing NEAL PATTISON & LUKE WARREN, PUB. CITIZEN CONG. WATCH, 2002 DRUG INDUSTRY PROFITS: HEFTY PHARMACEUTICAL COMPANY MARGINS DWARF OTHER INDUSTRIES, 1 (June 2003), *available at* http://www.citizen.org/documents/Pharma_Report.pdf).

[33] *Id.* at 11 (citing CONG. BUDGET OFFICE, HOW INCREASED COMPETITION FROM GENERIC DRUGS HAS AFFECTED PRICE AND RETURNS IN THE PHARMACEUTICAL INDUSTRY 28–31 (July 1998), *available at* http://www.cbo.gov/ftpdocs/6xx/doc655/pharm.pdf).

[34] *Id.* at 5–6 (citing Donald Light & Joel Lexchin, *Will Lower Drug Prices Jeopardize Drug Research? A Policy Fact Sheet*, 4 AM. J. BIOETHICS W1, W1–W4 (2004), *available at* http://www.bioethics.net/journal/j_articles.php?aid=61).

[35] U.S. CONST. art. VI, cl. 2.

[36] Crosby v. Nat'l Foreign Trade Council, 530 U.S. 363, 372 n.6 (2000) (citing 1 LAURENCE H. TRIBE, AMERICAN CONSTITUTIONAL LAW 1117 (Foundation Press 3d ed. 2000)).

[37] *See, e.g.*, Morales v. Trans World Airlines, Inc., 504 U.S. 374, 383, 391 (1992) (holding that the explicit language of a provision within the ADA expressly preempts certain state action).

[38] Fid. Fed. Sav. & Loan Ass'n. v. De la Cuesta, 458 U.S. 141, 153 (1982)

"where it is impossible for a private party to comply with both state and federal law[,]" or where a state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress."[39]

Conflict preemption inquiry examines the scheme of the "federal statute as a whole [in order to] identify[] its purpose and intended effects."[40] "[T]he Supreme Court has preempted state laws that . . . upset the balance [of federal patent protection] established by Congress."[41] The Excessive Pricing Act suffered conflict preemption because, in the Federal Circuit's view, it stood "as an obstacle to the federal patent law's balance of objectives as established by Congress."[42] In order to fully understand the analytical framework by which the Excessive Pricing Act was preempted, a historical overview of the principles of patent preemption is useful.

In 1964 the United States Supreme Court issued two "landmark intellectual property preemption decisions[]: *Sears, Roebuck & Co. v. Stiffel Co.* and *Compco Corp. v. Day-Brite Lighting*."[43] Together these two cases laid the doctrinal foundation for the scope of preemption in the field of federal patent law. In *Sears*, the district court relied upon Illinois's unfair competition law to prohibit the defendant from copying and marketing a pole lamp manufactured by Stiffel.[44] The Court of Appeals for the Seventh Circuit affirmed,[45] and the issue before the United States Supreme Court was "whether a State's unfair competition law can, consistently with the federal patent laws, impose liability for or prohibit the copying of an article which is protected by neither a federal patent nor a copyright."[46] In a unanimous opinion, the Court held that the Illinois unfair

(quoting Rice v. Santa Fe Elevator Corp., 331 U.S. 218, 230 (1947)).

[39] *Crosby*, 530 U.S. at 372, 373 (2000) (citing Hines v. Davidowitz, 312 U.S. 52, 67 (1941)).

[40] *Id.* at 373.

[41] Paul Heald, *Federal Intellectual Property Law and the Economics of Preemption*, 76 IOWA L. REV. 959, 967 (1991) (referencing Sears, Roebuck & Co. v. Stiffel Co., 376 U.S. 225, 231 (1964)).

[42] Biotechnology. Indus. Org. v. District of Columbia, 496 F.3d 1362, 1374 (Fed. Cir. 2007).

[43] David E. Shipley, *Refusing to Rock the Boat: The Sears/Compco Preemption Doctrine Applied to Bonito Boats v. Thunder Craft*, 25 WAKE FOREST L. REV. 385, 385–86 (1990).

[44] *Sears, Roebuck & Co.*, 376 U.S. at 226.

[45] *Id.* at 227.

[46] *Id.* at 225.

competition law was preempted by federal patent law:

> [T]he patent system is one in which uniform federal standards are carefully used to promote invention while at the same time preserving free competition. Obviously a State could not, consistently with the Supremacy Clause of the Constitution, extend the life of a patent beyond its expiration date or give a patent on an article which lacked the level of invention required for federal patents . . . . Just as a State cannot encroach upon the federal patent laws directly, it cannot, under some other law, such as that forbidding unfair competition, give protection of a kind that clashes with the objectives of the federal patent laws.[47]

In *Compco*, the district court relied upon the same Illinois unfair competition law to prohibit the defendant from selling florescent lighting fixtures that were "confusingly similar to[] those made by Day-Bright."[48] Again, the United States Supreme Court considered whether the state law conflicted with federal patent law by forbidding the copying of an unpatented design.[49] The Court reiterated its holding in *Sears*, "that when an article is unprotected by a patent or a copyright, state law may not forbid others to copy that article."[50] The Court reasoned that state laws forbidding copying "would interfere with the federal policy . . . of allowing free access to copy whatever the federal patent and copyright laws leave in the public domain."[51]

In *Sears* and *Compco*, the Supreme Court found that the Illinois unfair competition law was preempted because it conflicted with the federal policy to leave unprotected configurations in the public domain.[52] As a result, the *Sears* and *Compco* precedent established a firm focus on Congressional intent and underlying federal policy as the determinative measure of the preemptive scope of federal patent law.

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[47] *Id.* at 230–31 (footnotes omitted).

[48] Compco Corp. v. Day-Brite Lighting, Inc., 376 U.S. 234, 235–36 (1964) (stating how the district court "found that the overall appearance of Compco's fixture was 'the same, to the eye of the ordinary observer, as the overall appearance' of Day-Brite's reflector, which embodied the design of the invalidated patent," and thus "enjoined Compco 'from unfairly competing with plaintiff by the sale or attempted sale of reflectors identical to, or confusingly similar to' those made by Day-Brite").

[49] *Id.* at 234.

[50] *Id.* at 237 (referencing *Sears, Roebuck & Co*., 376 U.S. at 225).

[51] *Id.*

[52] Shipley, *supra* note 43, at 389–90 ("In essence, the state law prohibitions against copying struck down in *Sears* and *Compco* conflicted with federal policy. Congress intended unpatentable (and uncopyrightable) mechanical configurations to be free from restraint.").

In a series of cases following *Sears* and *Compco*, the United States Supreme Court developed the scope of patent preemption according to the federal policies underlying intellectual property protection. In *Kewanee Oil Co. v. Bicron Corp.*, the Court of Appeals for the Sixth Circuit held that an Ohio trade secret law was preempted because states "could not grant monopoly protection to processes and manufacturing techniques that were appropriate subjects for consideration . . . for a federal patent."[53] The Supreme Court reversed and held that the state trade secret law was not preempted by federal patent law.[54] The Court made it clear that a mere connection to intellectual property was insufficient grounds to preempt state law.[55] The Court explained that "[j]ust as the States may exercise regulatory power over writings so may the States regulate with respect to discoveries . . . . The only limitation . . . is that . . . regulation[] [in] the area of patents and copyrights . . . do[es] not conflict with the operation of [federal] laws in this area."[56]

The *Kewanee* Court also provided a thorough examination of the objectives of federal patent law. The Court began by emphasizing that the Constitutional objective for federal regulation of intellectual property is to "'promote the Progress of Science and useful Arts.'"[57] The Court explained that patent law promotes progress by offering a limited exclusive right as an incentive for inventors to undertake the potential risk of investing in research and development of new technology.[58] These innovations, motivated by the promise of exclusivity, have a positive impact on society by stimulating the employer and increasing the standard of living.[59] In return for the right to exclude, the patent laws require full disclosure of the invention so that the information is circulated to the public.[60] The Court reasoned that "such additions to the general store of knowledge are of such importance to the public weal that the Federal Government is willing to pay the high price of 17 years of exclusive use for its disclosure . . . in the art."[61] Finally, the

53 Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470, 474 (1974).
54 *Id.*
55 Shipley, *supra* note 43, at 390.
56 *Kewanee*, 416 U.S. at 479.
57 *Id.* at 480 (quoting U.S. CONST. art. I, § 8, cl. 8).
58 *Id.*
59 *Id.*
60 *Id.* at 480–81.
61 *Id.* at 481.

Court observed that patent law aims to prevent the removal of content from the public by action of the states.[62]

In *Aronson v. Quick Point Pencil Co.,* the Supreme Court reviewed the objectives delineated by *Kewanee* and found that the purposes of the federal patent system are essentially three-fold:

> First, patent law seeks to foster and reward invention; second, it promotes disclosure of inventions to stimulate further innovation and to permit the public to practice the invention once the patent expires; third, the stringent requirements for patent protection seek to assure that ideas in the public domain remain there for the free use of the public.[63]

The three-fold purpose of patent law distilled by *Aronson* demarcates the preemptive scope of patent law because conflict preemption is ultimately determined according to the objectives of federal law. The *Aronson* Court explained that the states may regulate intellectual property "in any manner not inconsistent with federal law."[64] State law will not suffer automatic displacement simply because it relates to intellectual property; however, if it interferes with the recognized objectives of patent law, then it will be preempted.[65]

In *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.* the Supreme Court cemented the preemptive scope of federal patent law when it addressed whether a Florida statute prohibiting duplication of an unpatented boat hull design was preempted by federal patent law.[66] The Court observed that "[t]he tension between the desire to freely exploit the full potential of our inventive resources and the need to create an incentive to deploy those resources is constant."[67] However, the Court emphasized that the federal patent system "embodies a *carefully crafted bargain* for encouraging the creation and disclosure of new, useful, and non-obvious advances in technology and design in return for the exclusive right to practice the invention for a period of years."[68] The Court cautioned that "state regulation of intellectual property must yield to the extent" that it interferes with the

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[62] *Id.*
[63] Aronson v. Quick Point Pencil Co., 440 U.S. 257, 262 (1979).
[64] *Id.*
[65] *Id.*
[66] Bonito Boats, Inc. v. Thunder Craft Boats, Inc., 489 U.S. 141, 144 (1989).
[67] *Id.* at 152.
[68] *Id.* at 150–51 (emphasis added).

balance of competing interests struck by patent law.[69]

As explained by Professor Paul Heald, it is "[t]he nature of the bargain" struck by patent law that determines the scope of federal preemption.[70] Although wealth maximization remains the ultimate goal of the patent system, *Bonito Boats* makes it clear that the bargain is crafted for the benefit of consumers.[71] For example, competitors are free to reverse engineer unpatented inventions because this process may yield improvements that ultimately benefit the public.[72] According to Heald, state laws are preempted only when they conflict with "the public interest-minded balance struck in patent law."[73]

c. State Power to Regulate Sale and Price

1. Police Power and Price Regulation

The United States "'Constitution created a Federal Government of limited powers,' while reserving a generalized police power to the States."[74] State police power encompasses "'the sovereign right of the Government to protect the lives, health, morals, comfort and general welfare of the people.'"[75] Although police power is broad and comprehensive, the real scope of such power is difficult to define.[76] Nevertheless, the state police power has been held to "extend[] to all matters which concern the regulation and control of the internal affairs of the state, and may even directly affect the internal affairs of a business or industry, as long as the legislation is neither arbitrary nor discriminatory."[77]

Many forms of price regulation fall squarely within the scope of state police power. For example, many states have direct price

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[69] *See id.* at 152 ("Where it is clear how the patent laws strike that balance in a particular circumstance, that is not a judgment the States may second-guess.").

[70] Heald, *supra* note 41, at 983 (citing *Bonito Boats*, 489 U.S. at 152).

[71] *Id.* (citing *Bonito Boats*, 489 U.S. at 146–50).

[72] *Id.* at 983–84 (citing *Bonito Boats*, 489 U.S. at 160).

[73] *Id.* at 984.

[74] United States v. Morrison, 529 U.S. 598, 618 n.8 (2000) (quoting New York v. United States, 505 U.S. 144, 155 (1992)).

[75] Allied Structural Steel Co. v. Spannaus, 438 U.S. 234, 241 (1978) (quoting Manigault v. Springs, 199 U.S. 473, 480 (1905)).

[76] 16A C.J.S. *Constitutional Law* § 611 (2008).

[77] *Id.* (referencing Perry v. S. Express Co., 81 So. 619 (Ala. 1919); State v. Hobson, 83 A.2d 846, (Del. 1951); 20th Century Ins. Co. v. Superior Court, 109 Cal. Rptr. 2d 611 (Cal. App. Dep't Super. Ct. 2001)).

regulations, similar to the Excessive Price Act, that prevent certain goods from being sold at an excessive or unconscionable price during particular times of crisis. In Virginia, it is unlawful for any person to sell or administer influenza vaccine at an unconscionable price during a vaccine shortage period.[78] In determining whether vaccine pricing is unconscionable, the law considers whether the price charged during the shortage period exceeds prices during the 10 days immediately prior to the shortage and whether the increase in the amount charged is attributable solely to additional costs incurred in obtaining the vaccine.[79]

In Alabama, it is illegal to charge unconscionable prices for commodities or rental facilities during a state of emergency.[80] Florida, South Carolina, and Maine each have similar "unconscionable price" regulations on the sale and rental of commodities during declared emergencies.[81] These restrictions on price gouging during periods of emergency demonstrate that price regulation falls squarely within the scope of state police powers when enacted to protect the health and general well-being of citizens.

2. Prescription Drug Price Regulation: The Maine Rx Program.

In 2000, the Maine Legislature enacted the Maine Act to Establish Fairer Pricing for Prescription Drugs, which established the Maine Rx Plus Program.[82] The Maine Rx Program was intended to reduce prescription drug prices for state residents by "enabl[ing] individuals to buy drugs from retail pharmacies at a discount roughly equal to the rebate on Medicaid purchases."[83]

The national Medicaid program authorized federal assistance to states that operated approved medical assistance plans to

[78] VA. CODE ANN. § 59.1-535 (2006) ("During any influenza vaccine shortage period, it shall be unlawful for any person to sell or administer, or to offer to sell or administer, influenza vaccine at an unconscionable price within the Commonwealth.").

[79] *Id.* §§ 59.1-535(1)–(3) (2006).

[80] ALA. CODE § 8-31-3 (2008).

[81] FLA. STAT. ANN. § 501.160 (West 2007); S.C. CODE ANN. § 39-5-145 (2007); ME. REV. STAT. ANN. tit. 10, § 1105 (Supp. 2007).

[82] ME. REV. STAT. ANN. tit. 22, § 2681 (2008); Pharm. Research and Mfrs. of Am. v. Walsh, 538 U.S. 644, 653 (2003).

[83] *Walsh*, 538 U.S. at 654.

reimburse the costs of medical treatment for needy individuals.[84] In 1990, the Omnibus Budget Reconciliation Act (OBRA) imposed a general requirement that drug companies must agree to provide rebates on their Medicaid sales of outpatient prescription drugs in order to qualify for Medicaid payments.[85] These rebates are calculated according to a statutory ratio measured by the average price at which the drug is sold.[86]

The Maine RX Program was established to use the Medicaid rebate system to reduce prescription drug prices in the state.[87] The program requires "any manufacturer . . . selling drugs in Maine through any publicly supported financial assistance program [to] 'enter into . . . a rebate agreement' with the State Commissioner of Human Services."[88] The Commissioner is directed to obtain rebates equal to those provided under OBRA.[89] Manufacturers pay these rebates into a fund administered by the Commissioner which is then distributed to participating pharmacies to offset the discounted sales price.[90] Essentially, the Maine Rx Program affords reduced prices to consumers by allowing pharmacies to sell at discounted prices and obtain reimbursement through rebate money paid to the State by prescription drug manufacturers.

Close examination of the Maine Rx Program reveals that it also contains a ban against profiteering in prescription drugs that is functionally equivalent to an excessive pricing restriction. Maine law provides that a manufacturer or distributor is engaged in illegal profiteering if it exacts an "unconscionable price" or demands prices that lead to "unjust or unreasonable profit."[91] To the extent that an excessive price constitutes an unconscionable price and generates unjust or unreasonable profits, Maine has enacted a general excessive price restriction on prescription pharmaceuticals.

The Pharmaceutical Research & Manufacturers of America

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[84] *Id.* at 650. *See also* 42 U.S.C. § 1396a (West 2008) (setting forth guidelines for state plans for medical assistance).

[85] *Walsh*, 538 U.S. at 652. *See also* 42 U.S.C. § 1396r-8 (West 2008) (establishing procedures for collecting payment for outpatient drugs).

[86] *Walsh*, 538 U.S. at 652. *See also* 42 U.S.C. §§ 1396r-8(c)(1)–(3) (West 2008) (prescribing rebates based on the average manufacturer's price).

[87] *Walsh*, 538 U.S. at 654.

[88] *Id.* (citing ME. REV. STAT. ANN. tit. 22, § 2681(3) (2002)).

[89] *Id.* (citing § 2681(4)).

[90] *Id.* (citing § 2681(6)).

[91] § 2697(2).

("PhRMA") brought action challenging the constitutionality of the Maine Rx Program.[92] In *Pharmaceutical Research & Manufacturers of America v. Walsh*, the United States Supreme Court considered whether the Maine RX Program was preempted by the federal Medicaid statutes.[93] The Court affirmed the lower court's ruling in favor of the Maine Rx Program and found that PhRMA had not carried its burden to show a probability of success on its preemption claims.[94] Although the Maine Rx Program was not evaluated in the context of preemption by federal patent law, the program shares a high degree of similarity to the District of Columbia's Excessive Pricing Act. Both laws perform the same function by providing point of sale price reductions on prescription pharmaceuticals at the expense of drug manufacturers.[95] As applied, both the Maine Rx Program and the Excessive Pricing Act have the effect of regulating the price of patented pharmaceuticals.[96] The absence of claims that the Maine Rx Program is preempted by the objectives of federal patent law may suggest that general state price restrictions on pharmaceuticals are not necessarily preempted by federal patent law.

3. State Laws Impeding the Sale of Patented Products

The Constitution does not expressly preclude states from regulating the price of patented products; "indeed, 'the federal patent laws do not create any affirmative right to make, use, or sell anything.'"[97] There are many instances where state laws impede patent holders from exploiting their exclusive rights in order to derive above-market profits on their patented goods. Two examples include state-wide bans on the sale and manufacture of goods and products liability actions. Both statutory product bans and products liability actions directly

92 Pharm. Research and Mfrs. of Am. v. Concannon, 249 F.3d 66, 72 (1st Cir. 2001).

93 *Walsh*, 538 U.S. at 661.

94 *Id.* at 670.

95 *See* D.C. CODE § 28-4554(a) (2008) (establishing a prima facie case for excessive pricing); *Walsh*, 538 U.S. at 654 (citing ME. REV. STAT. ANN. tit. 22, § 2681(3) (2008)) (explaining that drug manufacturers must enter into rebate agreements with the State Commissioner of Human Services).

96 *Walsh*, 538 U.S. at 654; § 28-4554(a).

97 Biotechnology Indus. Org. v. District of Columbia, 496 F.3d 1362, 1372 (Fed. Cir. 2007) (quoting Leatherman Tool Group, Inc. v. Cooper Indus., Inc., 131 F.3d 1011, 1015 (Fed. Cir. 1997)).

impair the ability of patent holders to receive the above-market profits that their exclusive right would otherwise provide.[98]

i. Statutory Product Bans

Many states have enacted statutory bans on the manufacture and sale of certain devices within their borders. These product bans inevitably preclude some patent holders from exploiting their exclusive right and receiving above-market profits in those jurisdictions. For example, certain states have enacted statutory bans on police radar jamming devices. In California, it is unlawful to "use, buy, possess, manufacture, sell, or otherwise distribute any device that is designed for jamming . . . any . . . electronic device used by a law enforcement agency to measure the speed of moving objects."[99] Both Colorado[100] and Oklahoma[101] also have similar bans on the manufacture and sale of radar jamming devices. According to the records of the United States Patent and Trademark Office, a number of patents incorporating radar or laser jamming technology have been issued.[102] However, state bans on the use and sale of such devices inevitably preclude these patent holders from the profits they could otherwise obtain in these markets.

Another common instance of statutory product ban prohibits the sale and manufacturer of slot machines and other gambling devices. In Alabama, a person commits the crime of possession of a gambling device if he manufactures, sells, or possesses a slot machine.[103] In Pennsylvania, it is a misdemeanor to sell slot

[98] *See, e.g.*, CAL. VEH. CODE § 28150(b) (West 2007) (prohibiting the manufacture of radar jamming devices); Louisiana Products Liability Act, LA. REV. STAT. ANN. §§ 9:2800.51–.52 (2008) ("This chapter establishes the exclusive theories of liability for manufacturers for damage caused by their products.").

[99] CAL. VEH. CODE § 28150(b) (West 2007).

[100] COLO. REV. STAT. ANN. § 42-4-1415(1)(a) (West 2008) ("No person shall use, possess, or sell a radar jamming device.").

[101] OKLA. STAT. ANN. tit. 47, § 11-808(C) (West 2008) ("It shall be unlawful to manufacture, advertise or offer for sale, sell or otherwise distribute any jammer in this state.").

[102] U.S. Patent No. 6,833,910 (filed May 1, 2002) (issued Dec. 21, 2004) ("A laser transponder for disabling a laser-based speed monitor . . . ."); U.S. Patent No. 7,023,374 (filed Oct. 6, 2002) (issued Apr. 4, 2006) (method and apparatus for signal detection and jamming); U.S. Patent No. 5,673,049 (filed Jan. 26, 1996) (issued Sep. 30, 1997) (police radar jammer).

[103] ALA. CODE § 13A-12-27(a)(1) (2008) ("A person commits the crime of possession of a gambling device if with knowledge of the character thereof he manufactures, sells, transports, places or possesses, or conducts or negotiates

machines and other devices to be used for gambling purposes.[104] In Tennessee, it is also a crime to knowingly own, manufacture or sell any gambling device or record.[105] United States Patent and Trademark Office records indicate a multitude of patented gambling devices.[106] Yet state laws in jurisdictions such as Tennessee, Alabama, and Pennsylvania prevent these gambling device patentees from deriving profits from their inventions in those markets.

ii. Products Liability Actions

Products liability is "[a] manufacturer's . . . tort liability for any damages or injuries suffered by a buyer, user, or bystander as a result of a defective product."[107] For patent holders, products liability impedes the level of profits that might otherwise be obtained through the exclusive right provided by a patent.[108] In some instances, products liability may result in the removal of a patented product from a state's market altogether.[109]

In the context of products liability cases, pharmaceutical manufacturers are widely protected by the learned intermediary

any transaction affecting or designed to affect ownership, custody or use of: (1) A slot machine . . . .").

[104] 18 PA. CONS. STAT. § 5513(a)(1) (2008).

> A person is guilty of a misdemeanor of the first degree if he: (1) intentionally or knowingly makes, assembles, sets up, maintains, sells, lends, leases, gives away, or offers for sale, loan, lease or gift, any punch board, drawing card, slot machine or any device to be used for gambling purposes, except playing cards . . . .

Id.

[105] TENN. CODE ANN. § 39-17-505(a)(1) (2006) ("A person commits an offense who knowingly owns, manufacturers, possesses, buys, sells, rents, leases, stores, repairs, transports, prints, or makes any gambling device or record.").

[106] *See generally* U.S. Patent No. 7,156,738 (filed Jan. 16, 2001) (issued Jan. 2, 2007) (casino gambling machine with bonus round award redemption); U.S. Patent No. 7,125,335 (filed Dec. 8, 2000) (issued Oct. 24, 2006) (casino gambling system with biometric access control); U.S. Patent No. 6,645,078 (filed Feb. 16, 2001) (issued Nov. 11, 2003) (casino gambling apparatus with person detection); U.S. Patent No. 5,702,302 (filed Sept. 21, 1995) (issued Dec. 30, 1997) (gambling machine with display means for the display of symbols).

[107] BLACK'S LAW DICTIONARY 1245 (8th ed. 2004).

[108] *See* State *ex. rel.* Johnson & Johnson Corp. v. Karl, 647 S.E.2d 899, 908 n.14 (W.Va. 2007) (showing the expenses drug manufacturers have endured to advertise to patients).

[109] Additionally, products liability may have also caused the removal of products without patent protection from the market. Paul H. Rubin, et al., *BMW v. Gore: Mitigating the Punitive Economics of Punitive Damages,* 5 SUP. CT. ECON. REV. 179, 194 (1997) (discussing a morning sickness drug that was removed from the market after a products liability suit).

doctrine. Due to the characterization of prescription drugs as "unavoidably unsafe," pharmaceutical manufacturers' liability is often limited to cases of inadequate warning of risks accompanying the product.[110] "Under the learned intermediary doctrine," prescription drug manufacturers have no duty to warn patients of the risks attributed to their products, "but instead ha[ve] a duty to warn the . . . doctor, who acts as a learned intermediary between the patient and the manufacturer."[111] However, where courts have applied an exception or declined to apply the learned intermediary doctrine altogether, products liability could conceivably serve as an impediment to the above-market profits typically afforded by a pharmaceutical patent.[112]

Outside of the protections afforded to pharmaceutical manufacturers, products liability serves as a sales and profits impediment to patent holders in general. In a Michigan case, *Estes v. Collier-Keyworth*, an 8-month-old infant suffered brain damage resulting in cerebral palsy and quadriplegia after his car seat failed to protect him in an automobile accident.[113] The plaintiff brought a products liability action against the manufacturer of the car seat, alleging that the product was defectively designed because it lacked the protective side head wings that were available on other models at the time.[114] The court awarded a verdict of approximately $16 million in favor of the plaintiff.[115]

In a Louisiana case, *Thompson v. Tuggle*, the decedent was killed "when [sic] chain saw he was using kicked back into his neck and severed his jugular vein."[116] The trial court found that

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[110] Stephen R. Kaufmann & Jason D. Johnson, *The Learned Intermediary Doctrine and Pharmaceutical Company Liability*, 95 ILL. B.J. 202, 203–04 (2007).

> Prescription drugs are in a class of products deemed "unavoidably unsafe." While there is no way to make prescription medications perfectly safe, their utility outweighs their potential risks in certain circumstances. Products that are "unavoidably unsafe" require an adequate warning accompanying the product or they may be considered unreasonably dangerous and defective, thus exposing the manufacturer to potential liability.

Id.

[111] McCombs v. Synthes, 587 S.E.2d 594, 595 (Ga. 2003).

[112] *See Karl*, 647 S.E.2d at 905 (examining the rationale behind twenty-two states' high courts declining to follow the learned intermediary doctrine).

[113] 28 ASS'N TRIAL LAW. AM. L. REP. 331 (1985).

[114] *Id.*

[115] *Id.*

[116] Thompson v. Tuggle, 486 So. 2d. 144, 144 (La. Ct. App. 1986).

the absence of a chain brake to prevent injury from kickbacks constituted an unreasonably dangerous design defect and entered a judgment of $255,800 against the manufacturer.[117] The Louisiana Court of Appeals upheld the manufacturer's liability for the design defect, but determined that the amounts awarded for loss of love, affection, and companionship were inadequate.[118] In light of the close relationship between the plaintiffs and the decedent, the court ordered the total award to be increased to $290,800.[119]

These products liability cases share a common element as instances where a manufacturer faced liability under state law for the intended design of their product. But they did not expressly examine whether the defective product was the subject of a federal patent, because liability would have been the same regardless of whether the manufacturer had patent protection.[120] Moreover, the very design features affording patentability and patent protection might also be the same design defects which lead to manufacturer liability for a particular product; yet, in such a case, the manufacturer would be unlikely to raise patent preemption as a defense.

d. The Excessive Pricing Act

On October 4, 2005 the District of Columbia City Council approved the Prescription Drug Excessive Pricing Act.[121] The Act was adopted after the District Council made findings that "[t]he excessive prices of prescription drugs . . . threaten[ed] the health and welfare of the residents of the District as well as the District government's ability to ensure that residents receive the health care they need."[122] The legislative history of the Excessive Pricing Act expressed the Council's purpose "to establish excessive pricing of prescription drugs as a violation of District law, to establish penalties for the excessive pricing prohibition, and to provide . . . an aggrieved party [with] a cause of action in a

117 *Id.* at 146.
118 *Id.* at 153.
119 *Id.*
120 *See generally* ASS'N TRIAL LAW. AM. L. REP., *supra* note 113, at 331 (omitting discussion of federal law in a products liability action brought in state court); *Thompson*, 486 So. 2d at 149 (discussing Louisiana state laws rather than federal law).
121 Prescription Drug Excessive Pricing Act of 2005, 2005 D.C. Sess. Law 16–37.
122 D.C. CODE ANN. § 28-4551(1) (LexisNexis 2001 & Supp.Mar. 2008).

court of competent jurisdiction."[123]

The Excessive Pricing Act represented an ambitious attempt by the District of Columbia to regulate the price of patented prescription drugs. The Act made it illegal for drug manufacturers "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."[124] The Act provided a judicial remedy from excessive drug pricing to "[a]ny affected party, including the District of Columbia" itself.[125]

Under the Excessive Pricing Act, a plaintiff could establish a prima facie case of excessive pricing by demonstrating that the wholesale price of a patented drug was "over 30% higher than the . . . price in any [other] high income country" where the drug was also protected by a patent.[126] Once the plaintiff established a prima facie case, the Act shifted the burden to the defendant drug manufacturer to prove that the price was not excessive given the "demonstrated costs of invention, development and production of the prescription drug, global sales and profits . . . , consideration of any government funded research that supported the development of the drug, and the impact of price on access to the prescription drug by residents and the government of the District of Columbia."[127] In the event of an excessive pricing violation, the Act provided a wide array of remedies including injunctions on the sale of the excessively priced drugs, fines, damages, costs of litigation, and other relief as deemed appropriate by the court.[128]

e. Biotechnology Industry Organization v. District of Columbia

The Excessive Pricing Act was met with strong resistance by the pharmaceutical industry. On October 12, 2005, only eight days after the Excessive Pricing Act was adopted, PhRMA filed

123 Prescription Drug Excessive Pricing Act of 2005.

124 § 28-4553 (emphasis added).

125 § 28-4555(a). An affected party is defined 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." § 28-4552(1).

126 § 28-4554(a). The Act limited the definition of "high income country" to Australia, Canada, Germany, and the United Kingdom. § 28-4552(2).

127 § 28-4554(b).

128 § 28-4555(b).

suit seeking declaratory relief from enforcement of the Act.[129] Only a few days later, the Biotechnology Industry Organization ("BIO") filed a similar suit against the District seeking the same relief as PhRMA.[130] The District of Columbia district court consolidated the BIO and PhRMA actions and held that the Excessive Pricing Act was preempted by federal patent law.[131]

The district court emphasized that "Congress' regulation of [the] pharmaceutical industry is grounded in . . . a complex balance of economic forces and regulatory exclusivity designed to encourage and reward the innovation, research, and development of new drugs."[132] According to the district court, the Act was designed to force patented drug manufacturers to choose between limiting their prices and facing "litigation over an undefined standard of 'excessiveness.'"[133] The district court concluded that "[p]unishing the holders of pharmaceutical patents in this manner flies directly in the face of a system of rewards calculated by Congress to insure the continued strength of an industry vital to our national interests."[134] In short, the Act was preempted because it stood as an obstacle to the objectives of federal patent law.[135]

The District of Columbia appealed to the United States Court of Appeals for the Federal Circuit, which affirmed that the Excessive Pricing Act was preempted by federal patent law.[136] The Federal Circuit conceded that the Constitution does not expressly preclude "states from regulating the price of patented goods," and that patent law does not ensure any affirmative marketing rights.[137] Nevertheless, the court maintained that

[129] Pharm. Research and Mfrs. of Am. v. District of Columbia, 406 F. Supp. 2d 56, 58–59 (D.D.C. 2005).

[130] Biotechnology Indus. Org. v. District of Columbia, 496 F.3d 1362, 1366 (Fed. Cir. 2007).

[131] *Pharm. Research and Mfrs. of Am.*, 406 F. Supp. 2d at 67.

[132] *Id.* at 65.

[133] *Id.* at 66.

[134] *Id.* at 66–67.

[135] *Id.* at 67, 71 (finding by the district court that the Excessive Pricing Act was unconstitutional because it violated the Interstate Commerce Clause as applied to transactions between parties not located within the District's borders. However, the District of Columbia did not appeal that portion of the decision and the implications of the interstate application of the Act are beyond the scope of this Note).

[136] Biotechnology Indus. Org. v. District of Columbia, 496 F.3d 1362, 1366 (Fed. Cir. 2007).

[137] *Id.* at 1372 (citing Leatherman Tool Group, Inc. v. Cooper Indus., Inc., 131 F.3d 1011, 1015 (Fed. Cir. 1997)).

such state price regulation is preempted "if it 'stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.'"[138]

The Federal Circuit pronounced that "'the essential criteria'" for its preemption analysis were "'the objectives of the federal patent laws.'"[139] The most fundamental of these objectives, the court explained, "is spelled out in the Constitution: 'To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.'"[140] After emphasizing the importance of the pecuniary rewards stemming from patents, the court reasoned that, in practical effect, "'the encouragement of investment-based risk is the fundamental purpose of the patent grant, and is based directly on the right to exclude.'"[141] The court explained that the right to exclude provides a strong incentive for drug companies to risk investment in new research and development efforts, and since this investment is made in expectation of receiving economic rewards during the period of exclusivity, "'the only limitation on . . . [this return] should be the dictates of the marketplace.'"[142]

The court recognized that the objectives of rewarding innovators with increased profits and maintaining reasonable prices "for consumers[ ]are in 'dialectic tension,'" but emphasized that Congress alone is charged with the responsibility for crafting a balance between these tensions.[143] According to the court, "[p]atentees value the right to exclude in part because the ability to foreclose competitors from making, using, and selling the invention may allow them an opportunity to obtain above-market profits during the patent's term."[144] However, "[o]nce the patent expires and the inventor's exclusive rights terminate, others may enter the market with products based on the teachings of the patent . . . . If the market functions properly, this new participation will bring down the formerly elevated

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[138] *Id.* (quoting Hines v. Davidowitz, 312 U.S. 52, 67 (1941)).

[139] *Id.* (quoting Hunter Douglas, Inc. v. Harmonic Design, Inc., 153 F.3d 1318, 1333 (Fed. Cir. 1998)).

[140] *Id.* (quoting U.S. CONST. art. I, § 8, cl. 8).

[141] *Id.* (quoting Sanofi-Synthelabo v. Apotex, Inc., 470 F.3d 1368, 1383 (Fed. Cir. 2006)).

[142] *Id.* at 1372–73 (quoting King Instruments Corp. v. Perego, 65 F.3d 941, 950 (Fed. Cir. 1995)).

[143] *Id.* at 1373.

[144] *Id.* at 1372.

price of the patented product to competitive levels."[145] The court concluded that, through the federal patent system, "Congress has decided that [the] patentees' present amount of exclusionary power, the present length of patent terms, and the present conditions for patentability represent the best balance between exclusion and free use."[146]

After addressing the objectives of federal patent law, the court turned to its analysis of the Excessive Pricing Act. Initially, the court conceded that patent rights are subordinate to the District's general police power over the property within its borders.[147] Nevertheless, the court made it clear that such general power must yield if it interferes with the specific enactments of Congress.[148] According to the court, the Excessive Pricing Act was "in no way general [because it] affect[ed] only patented [prescription drugs]."[149] The court found that "[b]y penalizing high prices—and thus limiting the full exercise of the exclusionary power that derives from a patent—the District ha[d] chosen to re-balance the statutory framework of rewards and incentives insofar as it relate[d] to inventive new drugs."[150] The court held that the Excessive Pricing Act was preempted because it attempted "to shift the benefits of a patented invention from inventors to consumers," and therefore, it stood as an "obstacle to the . . . balance of objectives" established by federal patent law.[151]

f. Petition for Rehearing Denied

On October 30, 2007, the Federal Circuit denied the District of Columbia's petition for panel rehearing and rehearing en banc.[152] Circuit Judge Dyk dissented and Circuit Judge Gajarsa issued a concurring opinion in response.[153] Gajarsa's concurrence lent its support to the panel's decision that the Excessive Pricing Act was preempted due to its conflict with federal patent law, specifically the Hatch-Waxman Act.[154] Gajarsa maintained that there was

145 *Id.* at 1373.
146 *Id.*
147 *Id.* (quoting Webber v. Virginia, 103 U.S. 344, 348 (1880)).
148 *Id.* (quoting Felder v. Casey, 487 U.S. 131, 138 (1988)).
149 *Id.*
150 *Id.* at 1374.
151 *Id.*
152 Biotechnology Indus. Org. v. District of Columbia, 505 F.3d 1343, 1343 (Fed. Cir. 2007).
153 *Id.* at 1344 (Gajarsa, J., concurring), 1348 (Dyk, J., dissenting).
154 *Id.* at 1345–46 (Gajarsa, J., concurring).

no need for reconsideration because the court's decision was not inconsistent with any prior precedent.[155] In his view "[t]he panel decision reached the correct result on the proper legal basis."[156]

Judge Gajarsa argued that the Hatch-Waxman Act embodies a federal policy allowing pharmaceutical patent holders to obtain economic rewards.[157] He argued that the right to exclude "is not granted in a vacuum or for its own sake," but rather to accomplish the Constitution's objective to promote innovation.[158] Gajarsa reasoned that "the primary mechanism by which the right to exclude promotes such innovation is by providing the patentee with the opportunity to obtain greater profits than it could have obtained without such a right to exclude."[159] According to Gajarsa, by extending the term of pharmaceutical patents to account for the delay of FDA approval, the Hatch-Waxman Act made it especially clear that the opportunity for above-market profits drive innovation in the pharmaceutical industry.[160] Gajarsa cited statements by Representative Henry Waxman and Senator Orrin Hatch as indicative of a clear Congressional purpose of the Hatch-Waxman Act to spur innovation by affording pharmaceutical patent holders the opportunity to obtain above-market profits.[161] Representative Waxman stated that "[a] patent is a monopoly, and when anyone holds a monopoly that person has the ability . . . to charge the highest price because there is no one else in competition . . . ."[162] Additionally, Senator Hatch stated that the Hatch-Waxman Act "add[s] stimulus for research on new drugs and medical devises [*sic*] . . . through an extension of patent life to help recover the costs of obtaining FDA approval."[163]

Judge Gajarsa argued that the Hatch-Waxman Act calibrated a precise balance between supporting the public's interest in affordable drugs and promoting innovation by increasing the

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155 *Id.* at 1344.

156 *Id.*

157 *Id.* at 1346.

158 *Id.*

159 *Id.*

160 *Id.*

161 *Id.* at 1346–47 (citing 130 CONG. REC. 15,846–47 (1984) (statement of Sen. Hatch); 130 CONG. REC. 23,058 (statement of Rep. Madigan); 130 CONG. REC. 23,058–59 (1984) (statement of Rep. Synar); 130 CONG. REC. 24,427 (1984) (statement of Rep. Waxman)).

162 *Id.* at 1346 (quoting 130 CONG. REC. 24,427 (1984) (statement of Rep. Waxman)).

163 *Id.* (quoting 130 CONG. REC. 15,846–47 (1984) (statement of Sen. Hatch)).

profit reward to pharmaceutical patent holders.[164] He maintained that the Hatch-Waxman Act "readjust[ed] . . . the scope of the patent right for pharmaceutical products represent[ing] the culmination of a 'long . . . effort to . . . balance [the] two objectives' of innovation and cost."[165] According to Gajarsa, the Excessive Pricing Act "directly target[ed] and undermin[ed] this careful balance" of objectives, and therefore it was appropriately subject to conflict preemption.[166] However, despite Gajarsa's unfavorable response to the Excessive Pricing Act, he left open the possibility of a drug price restriction that did not target patented products or did not upset the balance of patent rights.[167]

Judge Dyk's dissent argued that while the Excessive Pricing Act was preempted by federal patent law, the proper grounds for invalidation should have been field preemption rather than conflict preemption.[168] Dyk observed that since "the patent statutes contain no provision expressly preempting state regulation of the price of patented goods," the Excessive Pricing Act was preempted only if it either (1) regulated in an area of exclusive federal regulation (field preemption) or (2) regulated in a manner conflicting with federal policy (conflict preemption).[169]

According to Dyk, the Supreme Court's decision in *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, is laced with both field and conflict preemption.[170] The Supreme Court alluded to field preemption when it "found that [t]he patent statute's careful balance between public right and private monopoly to promote certain creative activity is a 'scheme of federal regulation . . . so pervasive as to make reasonable the inference that Congress left no room for the States to supplement it.'"[171] However, the Supreme Court applied conflict preemption when it concluded that the Illinois unfair competition law "conflict[ed] with the federal policy 'that all ideas in general circulation be dedicated to

164 *Id.* at 1347.

165 *Id.* (citing 130 CONG. REC. 23,058 (statement of Rep. Madigan)).

166 *Id.*

167 *Id.* at 1348.

168 *Id.* at 1349 (Dyk, J., dissenting).

169 *Id.* at 1348–49 (citing Biotechnology Indus. Org. v. District of Columbia, 496 F.3d 1362, 1372 (Fed. Cir. 2007); Cipollone v. Liggett Group, Inc., 505 U.S. 504, 516 (1992)).

170 *Biotechnology Indus. Org.*, 505 F.3d at 1349 (citing Bonito Boats, Inc. v. Thunder Craft Boats, Inc., 489 U.S. 141, 159–60 (1989)).

171 *Id.* (quoting *Bonito Boats*, 489 U.S. at 167).

the common good unless they are protected by a valid patent.'"[172] Dyk argued that the Excessive Pricing Act was subject to field preemption because it attempted to establish patent policy by requiring courts to determine what prices are sufficient to promote innovation.[173]

Dyk maintained that "a price discrimination provision presents no conflict with the purpose of . . . federal patent law," and therefore the panel's reliance on conflict preemption was inappropriate.[174] He insisted that the panel erred in finding conflict between the Excessive Pricing Act and "a supposed policy of the patent law to allow patent holders to reap maximum profits during the term of the limited monopoly on use of the invention."[175] Dyk argued that "[a] patent grant is designed not to allow the patent holder to exploit the grant for the maximum profit that the market will bear, but merely to confer a right of exclusivity."[176] According to Dyk, the Act did not conflict with federal policy because it did not interfere with the ability to exclude others.[177] In support of this conclusion, Dyk cited longstanding precedent that patent law does not preempt or conflict with state laws regulating or prohibiting the sale of patented products.[178] Dyk concluded that since that Hatch-Waxman Act was completely silent on the issue of state regulation of patented pharmaceutical prices, there is no clear indication that it changed this precedent.[179]

Finally, Dyk faulted the panel's failure to defer to the judicial presumption against preemption.[180] He insisted that in order to overcome this presumption, the proponent of preemption must show that "'the clear and manifest purpose of Congress' supports

[172] *Id.* at 1349 n.2 (quoting *Bonito Boats*, 489 U.S. at 159–60).
[173] *Id.* (citing D.C. CODE § 28-4554(b) (2008)).
[174] *Id.* at 1349–1350.
[175] *Id.* at 1350.
[176] *Id.*
[177] *Id.* at 1351.
[178] *Id.* at 1350–51 (citing Standard Sanitary Mfg. Co. v. United States, 226 U.S. 20, 49 (1912) (finding that patent rights did not preempt the price-fixing restrictions imposed by the Sherman Act); Webber v. Virginia, 103 U.S. 344, 347–48 (1880) (finding that the state tax was not preempted with regard to the sale of patented products); Patterson v. Kentucky, 97 U.S. 501, 505 (1878) (finding that patent rights were still subordinate to the state's statutory safety requirements).
[179] *Id.* at 1351.
[180] *Id.* (citing N.Y. State Conference of Blue Cross & Blue Shield Plans v. Travelers Ins. Co., 514 U.S. 645, 654–55 (1995).

preemption."[181] Dyk believed the Act aimed to promote public welfare, and therefore it fell within traditional state police power and triggered "a strong presumption against preemption."[182] According to Dyk, "[t]he patent laws were not designed to immunize patent holders from [such] legitimate state regulation."[183]

II. ANALYSIS

a. Preemptively Problematic: The Distorted Preemption Doctrine Applied in Biotechnology Industry Organization v. District of Columbia

In *Biotechnology Industry Organization*, the Federal Circuit took an unprecedented approach to patent preemption doctrine and effectively redefined the rights afforded to federal patent holders. First, the court misconstrued the exclusive right conferred by a patent in order to protect the ability of patent holders to receive market rewards. Second, the court distorted the Supreme Court's decision in *Bonito Boats Inc.* and therefore misinterpreted the "carefully crafted bargain" struck by Congress through the federal patent laws.[184] Finally, the court's holding implicates an overly restrictive view of the states' police power to regulate the sale and price of goods within their borders.

1. The court's misreading of patent law's exclusive right

The holding of *Biotechnology Industry Organization* misconstrued the exclusive right conferred by patent law in order to protect the ability of patent holders to exercise market power and receive economic rewards. The Federal Circuit held that state laws restraining the price of patented goods and diminishing the economic reward to patent holders are contrary to the objectives of patent law and therefore preempted.[185] The court emphasized that "[i]nventors are impelled to invest in creative effort by the expectation that, through procurement of a patent, they will obtain a federally protected 'exclusive

[181] *Id.* (quoting *N.Y. State Conference of Blue Cross*, 514 U.S. at 655).
[182] *Id.*
[183] *Id.*
[184] Bonito Boats, Inc. v. Thunder Craft Boats, Inc., 489 U.S. 141, 150 (1989).
[185] Biotechnology Indus. Org. v. District of Columbia, 496 F.3d 1362, 1374 (Fed. Cir. 2007).

right' . . . . [which] may allow them an opportunity to obtain above-market profits during the patent's term."[186] However, the exclusive right afforded by a patent should not be equated with a right to sell the patented product at an above-market price. Such an interpretation is contrary to the traditional understanding, adopted by the United States Supreme Court, that "[t]he franchise which the patent grants, consists altogether in the right to exclude everyone from making, using, or vending the thing patented, without the permission of the patentee. This is *all* that [the patentee] obtains by the patent."[187] This traditional understanding makes it clear that a patent grant does not provide patentees with a right to obtain economic rewards, but rather consists entirely of the ability to exclude others and only for a limited time.

The explanation of patent rights in *Biotechnology Industry Organization* is polluted by the opinion's inconsistent application of its own reasoning. The court began its preemption analysis by conceding that patent law does not "'create any affirmative right to make, use, or sell anything.'"[188] Yet the court's holding depended on the assumption that patent law does indeed afford such affirmative rights. The court found that the Excessive Pricing Act was preempted because by restraining patented pharmaceutical prices it limited "the full exercise of . . . exclusionary power that derives from a patent."[189] However, the exercise of such "exclusionary power" to charge higher prices necessarily implies not only market participation but the exercise of affirmative marketing rights. By suggesting that patents rights include the exercise of market power and an entitlement to market rewards, the Federal Circuit misconstrued

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[186] *Id.* at 1372.

[187] Bloomer v. McQuewan, 55 U.S. (1 How.) 539, 548 (1852) (emphasis added).

[188] *Biotechnology Indus. Org.*, 496 F.3d at 1372 (quoting Leatherman Tool Group, Inc. v. Cooper Indus., Inc., 131 F.3d 1011, 1015 (Fed. Cir. 1997)).

[189] *Id.* at 1374. It should be noted the court's original language "market power" was subsequently substituted for the term "exclusionary power" by an errata dated August 1, 2007. *See* Biotechnology Indus. Org. v. District of Columbia, No. 2006-1593, slip op. at 18 (Fed. Cir. 2007) (using the term "market power" to describe the exercise of patent rights), *available at* http://www.cafc.uscourts.gov/opinions/06-1593.pdf; *cf.* Errata for Biotechnology Indus. Org. v. District of Columbia (Fed. Cir. 2007), Appeal No. 2006-1593, (requesting replacement of the term "market power" on page 18 with the term "exclusionary power"), *available at* http://www.cafc.uscourts.gov/opinions/06-1593e.pdf.

the underlying objectives of patent law.

2. The court's misreading of *Bonito Boats Inc.*

The Federal Circuit distorted the precedent underlying Supreme Court's decision in *Bonito Boats* and therefore misinterpreted the substance of the "carefully crafted bargain" struck by federal patent law.[190] In *Bonito Boats* the Court observed that "[t]he tension between the desire to freely exploit the full potential of our inventive resources and the need to create an incentive to deploy those resources is constant."[191] The Court explained that where patent law strikes a clear balance between these tensions, it "is not a judgment the States may second-guess."[192] As a result, *Bonito Boats* made it clear that state regulation "must give way when it clashes with the balance" struck by patent law "between encouraging invention . . . [and] allowing exploitation."[193]

In *Biotechnology Industry Organization*, the Federal Circuit adopted an unjustifiably broad understanding of the "carefully crafted bargain" referred to by the Supreme Court in *Bonito Boats*.[194] The Federal Circuit concluded that "[t]he underlying determination about the proper balance between innovators' profit and consumer access to medication . . . is exclusively one for Congress to make . . . . [and] 'is not a judgment the States may second-guess.'"[195] Such a conclusion distorts the reasoning of *Bonito Boats*. Patent law, in general, does not strike a clear "balance between innovators' profits and consumer access to" patented goods.[196] Rather, according to *Bonito Boats* the "patent system . . . embodies a carefully crafted bargain for encouraging . . . advances in technology and design *in return for the exclusive right to practice the invention for a period of years*."[197] Patent law resolves the dialectic tension between promoting and exploiting innovation by striking a balance

190 Bonito Boats, Inc. v. Thunder Craft Boats, Inc., 489 U.S. 141, 150 (1989).
191 *Id.* at 152.
192 *Id.*
193 Shipley, *supra* note 43, at 404 (citing *Bonito Boats*, 489 U.S. at 152).
194 *Bonito Boats,* 489 U.S. at 150.
195 Biotechnology Indus. Org. v. District of Columbia, 496 F.3d 1362, 1374 (Fed. Cir. 2007) (quoting *Bonito Boats*, 489 U.S. at 152).
196 *See Bonito Boats*, 489 U.S. at 149 (arguing that an innovator has the option of choosing to patent his innovation in hope of gaining profit or dedicate his idea to the public at large).
197 *Id.* at 150–51 (emphasis added).

between exclusion and free use.[198] Although encouraging innovation is a primary objective of the patent system, it is the right to exclude, rather than the affirmative right to market a product, that Congress has chosen as the specific means to effectuate this objective.[199] By suggesting that Congress has struck a clear balance in a circumstance where it has not, the holding of *Biotechnology Industry Organization* failed to account for the specific means selected by Congress to promote innovation in technology and design.

In *Biotechnology Industry Organization*, the Federal Circuit complained that the Excessive Pricing Act "shift[ed] the benefits of a patented invention from inventors to consumers."[200] However, as pointed out by Professor Heald, the Supreme Court's references in *Bonito Boats* made it clear that the bargain of the patent system is crafted to favor consumers.[201] In *Bonito Boats* the Court explained that "the ultimate goal of the patent system is to bring new designs and technolog[y] into the public domain through disclosure."[202] Thus, the primary objective of the patent system is to ensure that innovative technology is introduced into the public domain, and the reward to innovators is only secondary. By holding public welfare subordinate to inventor rewards, *Biotechnology Industry Organization* failed to adhere to the "public interested-minded balance" envisioned by *Bonito Boats*.[203]

3. The court's failure to defer to state police power

The Federal Circuit's decision in *Biotechnology Industry Organization* adopted an overly narrow approach to the scope of the states' police power to regulate for the health, safety, and general welfare of their citizens. As the Supreme Court explained in *PhRMA v. Walsh*, a proper inquiry begins "with a presumption that the state statute is valid . . . and ask[s] whether [the] petitioner has shouldered the burden of overcoming that presumption."[204] With respect to the

198 *See id.* at 148–52.
199 *See id.* at 148–50.
200 *Biotechnology Indus. Org.*, 496 F.3d at 1374.
201 Heald, *supra* note 41, at 983 (citing *Bonito Boats*, 489 U.S. at 147–50).
202 *Bonito Boats*, 489 U.S. at 151.
203 Heald, *supra* note 41, at 984 (citing *Bonito Boats*, 489 U.S. at 150–51).
204 Pharm. Research and Mfrs. of Am. v. Walsh, 538 U.S. 644, 661–62 (2003) (citation omitted).

relationship between state police power and patent preemption, traditional precedent had deferred to legitimate state regulation:

> Congress never intended that the patent laws should displace the police powers of the States, meaning by that term those powers by which the health, good order, peace, and general welfare of the community are promoted. Whatever rights are secured to inventors must be enjoyed in subordination to this general authority of the State over all property within its limits.[205]

As a result, there is no indication that federal patent law restricts the power of a state to "regulate a business in any of its aspects, including the prices to be charged for the products or commodities it sells."[206]

Many states have enacted laws that restrict the sale and price of patented products both directly and indirectly. Statutory product bans directly prevent inventors of patented radar detectors and gambling devices from obtaining the economic rewards that their patents might otherwise provide.[207] Products liability actions often indirectly result in a similar exclusion of patented products from markets where patent holders could otherwise obtain rewards.[208] Unconscionable pricing restrictions diminish the ability of patent holders to charge high prices on their products during periods of emergency.[209] Each of these state laws identifies an aspect of a product that is detrimental to the welfare of state citizens as grounds for regulating the sale or price of the product. In every case, it is immaterial whether the affected product is patented or not. Price restrictions on pharmaceuticals should be no different.

b. Square Pegs and Round Holes: Fitting the Excessive Pricing Act into the Categorical Preemption Doctrines

One of the main problems the Federal Circuit faced in *Biotechnology Industry Organization* was that the Excessive Pricing Act failed to fit neatly into any of the categorical preemption doctrines.[210] By expressly targeting patented

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[205] Webber v. Virginia, 103 U.S. 344, 347–48 (1880).

[206] Nebbia v. New York, 291 U.S. 502, 537 (1934); *accord* Brief for the National Legislative Association on Prescription Drug Prices et al., *supra* note 27, at 17.

[207] *See supra* notes 97–106 and accompanying text.

[208] *See supra* notes 108–20 and accompanying text.

[209] *See supra* notes 78–81 and accompanying text.

[210] Biotechnology Indus. Corp. v. District of Columbia, 505 F.3d 1343, 1345 (Fed. Cir. 2007).

pharmaceuticals, the Excessive Pricing Act practically invited – indeed even provoked – a finding of preemption. Despite this foregone conclusion, however, the court found that express preemption did not apply and experienced difficulty resolving the Excessive Pricing Act under both conflict and field preemption.[211]

The Excessive Pricing Act directly offended the fundamental principles of federalism recognized by the United States Supreme Court more than 200 years ago in *McCulloch v. Maryland*.[212] In *McCulloch*, the State of Maryland enacted a tax on all banks in the state not chartered by the legislature.[213] The only bank in the state effectively subject to the tax was the Bank of the United States incorporated by Congress under federal law.[214] The United States Supreme Court held:

> [T]he States have no power, by taxation or otherwise, to retard, impede, burden, or in any manner control, the operations of the constitutional laws enacted by Congress to carry into execution the powers vested in the general government. This is . . . the unavoidable consequence of that supremacy which the constitution has declared.[215]

Much like the state tax against the federal bank in *McCulloch*, the Excessive Pricing Act targeted a creation of federal law to bear the burden of promoting state interests. *McCulloch* made it clear that states are restrained from impeding federal enactments in this manner:

> "[A tax on the federal bank] stops the very source of its circulation and life. It is as much a direct interference with the legislative faculty of Congress, as would be a tax on patents, or copy rights, or custom-house papers, or judicial proceedings."[216]

Although the Excessive Pricing Act fell short of a state tax on patents, it nonetheless obstructed federal patent rights in a manner which the Constitution prohibits.

Despite the conclusion that the Excessive Pricing Act directly offended the Constitution, it remained difficult to determine precisely what form of preemption is most appropriate. The

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[211] *Id.* ("That the D.C. Act could also be considered preempted by 'field preemption' because it impermissibly establishes new patent policy, only strengthens the panel's determination that there is a direct conflict between the D.C. Act and . . . federal patent laws.").

[212] McCulloch v. Maryland, 17 U.S. (1 Wheat.) 316, 436–37 (1819).

[213] *Id.* at 320.

[214] *Id.* at 436.

[215] *Id.*

[216] *Id.* at 399.

patent laws contain no preemption provision and therefore express preemption was clearly inappropriate.[217] However, the Excessive Pricing Act failed to fit neatly within either conflict or field preemption doctrine.

1. Conflict Preemption

The Excessive Pricing Act was not a clean fit for conflict preemption because it did not necessarily stand as a clear obstacle to the traditional objectives of patent law. As previously discussed, the objectives of patent law are threefold: (1) to provide an incentive to invent, (2) to promote full disclosure of inventions, and (3) to ensure that the content of the public domain cannot be removed by the states.[218]

First, the Excessive Pricing Act did not impede patent law's objective to protect the content of the public domain from interference by the states. The Act did not afford any copy protection or exclusionary rights that might abridge free exploitation of the public domain.[219]

Second, the Excessive Pricing Act did not clearly obstruct patent law's remaining objectives to provide an incentive for innovation and full disclosure. Patent law promotes innovation by providing the opportunity for patent holders to create an exclusive market free from competition, but not necessarily by allowing them to charge higher prices, although this is often the result.[220] Simply put, the difference is a matter of being the sole participant in an exclusive market as opposed to a competitor in an open market. Although restricting unit prices could conceivably reduce profit levels, it would not completely destroy the ability of patent holders to achieve substantial rewards.[221] Nothing in the Excessive Pricing Act limited the overall amount of profit that pharmaceutical patent holders were permitted to

[217] *See* Biotechnology Indus. Org. v. District of Columbia, 496 F.3d 1362, 1372 (Fed. Cir. 2007) (stating that the patent statute contained no express provision prohibiting the "states from regulating the price of patented goods.").

[218] Dow Chem. Co. v. Exxon Corp., 139 F.3d 1470, 1474 (Fed. Cir. 1998) (citing Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470, 480–81 (1974)).

[219] Biotechnology Indus. Corp. v. District of Columbia, 505 F.3d 1343, 1351 (Fed. Cir. 2007).

[220] *Id.* at 1350.

[221] *See generally* Helmut F. Furth, *Price-Restrictive Patent Licenses Under the Sherman Act*, 71 HARV. L. REV. 815, 816 (1958) ("Only if the patent or its products are in greater demand, are cheaper to produce, or tap hitherto unexploited sources of profit, can [the patentee] anticipate a greater reward.").

collect in their exclusive markets.[222] As exclusive market participants, pharmaceutical patent holders could have continued to obtain higher profits by virtue of increased sales volumes. Rather than facing competition for market share, only the patent holder would be allowed to fulfill the entire demand for a particular pharmaceutical. The opportunity for pharmaceutical manufacturers to reserve an exclusive market by foreclosing competitors should afford adequate incentive to spur innovation and disclosure.

Judge Gajarsa's concurring opinion revealed the difficulty in applying conflict preemption to the Excessive Pricing Act. In order to bolster support for his initial finding of conflict preemption, Judge Gajarsa was forced to reach outside the traditional patent preemption doctrine and place special emphasis on the policies embodied by the Hatch-Waxman Act.[223] Essentially, Judge Gajarsa interpreted the Hatch-Waxman Act as expressing a fourth objective of federal patent law: to strike a balance between innovation and cost for patented pharmaceuticals.[224] Since the Excessive Pricing Act directly targeted and undermined the "careful balance between innovation and drug costs," Judge Gajarsa found that it stood as an obstacle to this fourth objective of patent law and, therefore, was subject to conflict preemption.[225]

It is unclear, however, whether the Hatch-Waxman Act serves as a justifiable basis for conflict preemption of the Excessive Pricing Act. The Federal Circuit has stated that the Hatch-Waxman Act "struck a balance between two competing policy interests: (1) inducing pioneering research and development of new drugs and (2) enabling competitors to bring low-cost, generic copies of those drugs to market."[226] The Hatch-Waxman Act balanced this tension by affording a limited patent term extension to brand name manufacturers while relaxing the barriers to generic drug approval.[227] As Judge Dyk's dissent pointed out however, "[t]here is not a word in the cited legislative

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[222] Law of Dec. 10, 2005, tit. 28, ch. 45B, § 2, 2005 D.C. Laws ch. 45B, invalidated by *Biotechnology Indus. Org.*, 496 F.3d at 1362 (explaining what the Excessive Pricing Act entailed).

[223] *Biotechnology Indus. Org.*, 505 F.3d at 1347.

[224] *Id.*

[225] *Id.*

[226] Allergan, Inc. v. Alcon Labs., 324 F.3d 1322, 1325 (Fed. Cir. 2003) (citing Andrx Pharms., Inc. v. Biovail Corp., 276 F.3d 1368, 1371 (Fed. Cir. 2002)).

[227] *Id.* at 1325.

history of the Hatch-Waxman Act suggesting any concern about state price regulation of patented pharmaceutical products."[228] Gajarsa's conclusion that the Excessive Pricing Act conflicted with the Hatch-Waxman Act failed to recognize that the Hatch-Waxman Act was only a limited means to balance competing policy interests for the development of new pharmaceuticals. Because the Excessive Pricing Act did not interfere with the Hatch-Waxman Act's patent term extension or relaxed generic approval standards, it is not clear that the two laws were in actual conflict.

2. Field Preemption

In his dissent, Judge Dyk argued that field preemption was an appropriate basis for invalidating the Excessive Pricing Act.[229] Dyk explained that the Act sought to "establish patent policy" by requiring local courts to determine the prices necessary to promote innovation, and therefore the Act was subject to field preemption.[230] In support of this conclusion, Dyk cited the Supreme Court's language in *Bonito Boats* that patent law is "'so pervasive . . . that Congress left no room for the States to supplement it.'"[231] According to Dyk, all state regulation in the field of patents would likely be subject to field preemption.[232]

Despite the Supreme Court's language in *Bonito Boats*, it is unlikely that field preemption of patent law was an appropriate basis for invalidating the Excessive Pricing Act. As one commentator has stated, "[t]he weights are stacked against implied field preemption because the judicial utilization of the doctrine would imply that congressional action has been so complete in the field of intellectual property law that there is no room for state regulation."[233] Moreover, field preemption of patent law would be inconsistent with the Supreme Court's holdings in *Kewanee Oil Co. v. Bicron Corp*. and *Aronson v. Quick Pencil Point Co*. In *Kewanee*, the Court noted that the states

[228] *Biotechnology Indus. Org.*, 505 F.3d at 1351 (Dyk, J., dissenting).

[229] *Id.* at 1349.

[230] *Id.*

[231] *Id.* at 1349 (citing Bonito Boats, Inc. v. Thunder Craft Boats, Inc., 489 U.S. 141, 167 (1989)).

[232] *Id.* at 1348.

[233] Christopher T. Blackford, *Attention Shoppers: The Federal Circuit's Failure to Preempt Contractual Provisions Prohibiting Reverse Engineering May Create a Blue Light Special on Jurisdictional Forums*, 57 SMU L. REV. 63, 71 (2004).

were not foreclosed from regulating in the field of intellectual property.[234] Later in *Aronson*, the Supreme Court reaffirmed this position when it explained that "the states are free to regulate the use of such intellectual property in any manner not inconsistent with federal law."[235] The Supreme Court's decisions in *Kewanee* and *Aronson* indicate that field preemption in a patent context is practically "a dead body of law," and therefore, conflict preemption is the only likely obstacle to the Excessive Pricing Act.[236]

c. The Fate of the Excessive Pricing Act

If the Excessive Pricing Act was revised to apply generally to all pharmaceuticals rather than targeting only those protected by patents, the Act would probably not be subject to preemption. In order to withstand preemption, the Act must apply even-handedly to both patented and non-patented prescription drugs. This could probably be accomplished by simply revising the Act's operative provision to omit the express reference to "patented prescription drug[s]."[237] In addition, the Act should refrain from comparing allegedly excessive prices to the price "in any high income country in which the product is protected by patents or other exclusive marketing rights."[238] Support for the conclusion that pharmaceutical price restrictions could withstand patent preemption can be found in the opinions of Federal Circuit Judges Gajarsa and Dyk, as well as in the Supreme Court's ruling in favor of the Maine Rx Program.[239] Finally, the validity of other state laws, such as statutory product bans, products liability actions, and unconscionable pricing restrictions, all of which may adversely affect some patent holders, indicates that general price restrictions should be upheld.

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[234] *Id.* *See also* Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470, 479 (1974) (finding States may have regulatory powers relating to discoveries, and particularly, "States may hold diverse viewpoints in protecting intellectual property relating to invention as they do in protecting the intellectual property relating to the subject matter of copyright.").

[235] Aronson v. Quick Point Pencil Co., 440 U.S. 257, 262 (1979).

[236] Blackford, *supra* note 233, at 72 (arguing that the Court's holding in *Aronson* "does not preclude . . . conflict preemption.").

[237] D.C. CODE ANN. § 28-4553 (LexisNexis Supp. 2008).

[238] D.C. CODE ANN. § 28-4554(a) (LexisNexis Supp. 2008).

[239] *See* Biotechnology Indus. Org v. District of Columbia, 505 F.3d 1343, 1348 (Fed. Cir. 2007) (Gajarsa, J., concurring), 1349–51 (Dyk, J., dissenting); Pharm. Research & Mfrs. of Am. v. Walsh, 538 U.S. 644, 649, 668–69 (2003).

In Gajarsa's concurrence on denial of rehearing, he specifically noted that the issue before the panel was not premised on whether the District has authority to impose general price discrimination restrictions.[240] Gajarsa emphasized that the panel did not pass judgment on the issue of "future efforts of states to regulate drug prices, which for example did not only target patent drugs or did not as significantly or directly undermine the balance of the federal patent right . . . ."[241] Dyk's dissent on denial of rehearing took a clear position to uphold a general price regulation. Dyk argued that to the extent that the Act was designed to prohibit price discrimination, there was "no conflict with federal policy."[242] In fact, Dyk faulted the panel's opinion for suggesting that even "legitimate price regulation" was invalid.[243]

The fact that the Supreme Court rejected a challenge to the Maine Rx Program[244] probably weighs in favor of upholding general price restrictions. Although the Court did not address whether the Maine Rx Program was preempted by patent law,[245] the absence of a patent preemption challenge probably indicates the relative weakness of such a claim.[246]

Finally, the validity of state laws such as statutory product bans, products liability actions, and unconscionable pricing restrictions indicate that general price restrictions should be upheld.[247] Although these state laws restrict the ability of some patent holders to obtain economic rewards from their inventions, they do so without discriminating between patented and non-patented products. So long as pharmaceutical price restrictions do not discriminate against patented products they should be able to withstand preemption.

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[240] *Biotechnology Indus. Org.*, 505 F.3d at 1347–48 (Gajarsa, J., concurring).

[241] *Id.* at 1348.

[242] *Id.* at 1349 (Dyk, J., dissenting).

[243] *Id.* at 1348.

[244] *See Pharm. Research and Mfrs. of Am.*, 538 U.S. at 667 (2003) (Stevens, J., concurring) ("[T]he mere fact that prior authorization may impose a modest impediment to access to prescription drugs provided at government expense does not provide a sufficient basis for pre-emption of the entire Maine Rx Program.").

[245] *See id.* at 670 (affirming the judgment of the Court of Appeals in denying petitioner's request for injunctive relief since petitioners failed to produce enough evidence in its claim that federal law pre-empted Maine's RX program).

[246] *See supra* text accompanying notes 92–96.

[247] *See supra* text accompanying notes 77–120.

III. CONCLUSION

The Federal Circuit's determination that the Excessive Pricing Act was preempted by federal law proved to be a difficult task. It is apparent from the Constitution that state laws directly targeting patented products should be preempted by federal patent law. Determining the specific mode of preemption, however, proved exceedingly difficult, and the Federal Circuit's reliance on conflict preemption created a number of inconsistencies between the scope of patent rights and state police power. The court's opinion in *Biotechnology Industry Organization* improperly equated patent rights with an entitlement to obtain market rewards, misconstrued the carefully crafted bargain embodied by the federal patent system, and adopted an overly narrow view of state police power. While the concurring and dissenting opinions on rehearing attempt to resolve the weakness of *Biotechnology Industry Organization* decision, both ultimately fell short of providing a clear solution. The Hatch-Waxman and the Excessive Pricing Act are not in clear conflict with one another, and field preemption is practically a dead body of law in the context of patents. Moreover, neither the Hatch-Waxman Act nor field preemption are likely to serve as a viable basis for invaliding laws that target patented products other than pharmaceuticals.

Although the Excessive Pricing Act was preempted by federal patent law, it is likely that general pharmaceutical price restrictions would not suffer preemption. Circuit Judge Dyk clearly favored upholding general price restrictions, and Circuit Judge Gajarsa remained open to the same conclusion. Moreover, the validity of the Maine Rx Program, as well as other state laws restricting the sale of patented goods, indicate that general pharmaceutical price restrictions would not be preempted. The fate of the poorly drafted Excessive Pricing Act should not preclude the validity of legitimate state price restrictions on prescription pharmaceuticals.

Christopher Lea Lockwood ∗

∗ J.D candidate, 2009, University of Georgia School of Law; B.A. Philosophy, 2005, Mercer University. The author thanks Professor Paul Heald for introducing him to this topic and for his guidance and encouragement, and also thanks John Hackney for his invaluable assistance and input.