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# Patent Preemption Exceptionalism

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*U.S. prescription drug prices are the highest in the world, posing challenges for individuals to afford medicine and for governments to subsidize health insurance. In an absence of federal regulation, states have taken steps to regulate drug prices within their borders. Yet in* BIO v. DC*, the Federal Circuit held that patent law preempted a D.C. law that prohibited sales of patented drugs at excessive prices. Armed with that precedent, drug companies are now challenging state efforts to regulate drug prices in other ways, such as through affordability boards.*

*This Article contends that the* BIO v. DC *decision is an example of exceptionalist decision-making for pharmaceutical patents in multiple ways. It is inconsistent with Supreme Court precedent about preemption based on patent law, preemption in the pharmaceutical industry, and preemption of state price regulation. In each of these areas, the Supreme Court has been reluctant to find state law implicitly preempted based on speculative arguments about how state programs might impact federal policy goals, particularly when there is no countervailing federal regulation. Departing from this general guidance, the Federal Circuit created a special rule for patented drugs, based on vague legislative history and speculation about how state regulation may impact innovation policy goals.*

*Exceptionalism for pharmaceutical patents is misguided. Governing statutes provide no sound reason for treating pharmaceutical patents differently from other patents or other forms of regulation. Moreover, preemption involves trans-substantive questions about statutory interpretation that do not depend on the Federal Circuit's technical expertise regarding patent law. Given the Supreme Court's track record of reversing exceptionalist rules created by the Federal Circuit, the exceptionalist nature of* BIO v. DC *may help gain traction for either the Federal Circuit or the Supreme Court to reconsider the decision. Either court should do so because the decision harms state sovereignty and allows drug companies to exercise considerable market power without direct regulatory oversight of prices.*

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## INTRODUCTION

U.S. prescription drug prices are the highest in the world, making medications difficult for many Americans to afford[1] and

[1] Grace Sparks et al., *Public Opinion on Prescription Drugs and their Prices*, KFF Figs. 4-6 (2024), https://www.kff.org/health-costs/public-opinion-on-prescription-drugs-and-their-prices/.

creating significant expenses for governments.[2] Drugs prices therefore have become a major political issue. Recent federal reforms have targeted high drug prices. In 2022, Congress created the Medicare Drug Price Negotiation Program, which gives the Centers for Medicare and Medicaid Services ("CMS") authority to negotiate prices for Medicare for a limited number of drugs that have been on the market for years without competition.[3] In 2025, the Trump Administration entered into deals with pharmaceutical companies and proposed Medicare payment models to align U.S. prices with lower prices offered in other countries.[4] The impact of these reforms, which predominantly focus on prices for Medicare and its beneficiaries, remains yet to be seen.[5] In the meantime, many people still struggle to afford essential medicines, and taxpayers remain on the hook for big bills for prescription drugs.[6]

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[2] Elizabeth Schrier et al., *Taxpayers' Share of US Prescription Drug and Insulin Costs: A Cross-Sectional Study* J. Gen. Intern. Med. 1325, 1329 (2024) ("Taxpayers pay for 58.76% of all outpatient retail prescription drugs.").

[3] Inflation Reduction Act, Pub. L. 117-169, Secs. 1191-98 (Aug. 16, 2022). The IRA also limited out-of-pocket costs and required rebates for prices increases above inflation. Juliette Cubanski, Tricia Neuman, & Meredith Freed, *Explaining the Prescription Drug Provisions in the Inflation Reduction Act*, KFF (2023), https://www.kff.org/medicare/explaining-the-prescription-drug-provisions-in-the-inflation-reduction-act/.

[4] *See* President Donald J. Trump Announces Largest Developments to Date in Bringing Most-Favored-Nation Pricing to American Patients (Dec. 19, 2025) (announcing nine agreements to provide most favored nation prices to State Medicaid programs and discounts on direct-to-consumer sales); Kristi Martin & Rachel Sachs, *Administration Releases Proposed Medicare International Drug Reference Pricing Models*, HealthAffairs Forefront (2025).

[5] *See, e.g.*, Rachel Sachs, *Prescription Drug Policy, 2025 and 2026: The Year in Review and the Year Ahead*, HealthAffairs Forefront (2026), https://www.healthaffairs.org/content/forefront/prescription-drug-policy-2025-and-2026-year-review-and-year-ahead (describing legal challenges to price negotiation program and implementation issues regarding agreements). In 2025, Congress expanded the exemption from Medicare price negotiation for drugs with orphan designations, which may significantly limit the scope of the program. Kristi Martin, Emma Cousin, & Sean Sullivan, *Blockbusters and Loopholes: Expanding Exemptions in Medicare Drug Price Negotiations*, KFF (2025).

[6] Grace Sparks et al., *Public Opinion on Prescription Drugs and their Prices*, KFF Fig. 6 (2024), https://www.kff.org/health-costs/public-opinion-on-prescription-drugs-and-their-prices/ (reporting that three in ten people do not take medicine as prescribed due to costs); Schrier, *supra* note 2, at 1328

Enbrel, a drug used to treat autoimmune conditions such as rheumatoid arthritis, provides an illustrative example. Although the FDA first approved Enbrel in 1998,[7] Enbrel remains very expensive.[8] In 2022, the average yearly cost in the state of Colorado for Enbrel was $46,772 per patient.[9] Enbrel does not yet face competition from generic competitors; patents covering the drug do not expire until 2029.[10] Given the high cost and lack of competition, CMS selected Enbrel for the first round of Medicare price negotiation.[11] A negotiated fair price went into effect for Medicare beneficiaries this year.[12] Yet that negotiated price will not cover many other patients who are not insured through Medicare. For patients with commercial insurance, there is no federal regulation of prescription drug prices. Enbrel, therefore, will likely remain very expensive for many patients, despite Medicare price negotiation. Out-of-pocket costs with commercial insurance typically average around several thousand dollars per year.[13]

In contexts where there is no federal regulation of drug prices, states have started stepping in. Responding to concerns that excessive costs are making drugs unaffordable for patients and putting pressure on state government budgets, state legislatures have passed a variety

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(describing billions of dollars of indirect payments by federal, state, and local governments for prescription drugs through private insurance payments).

[7] Enbrel, Drugs@FDA: FDA-Approved Drugs, https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=BasicSearch.process.

[8] COLORADO PRESCRIPTION DRUG AFFORDABILITY BOARD, 2023 AFFORDABILITY REVIEW SUMMARY REPORT: ENBREL 2 (2024) (hereinafter "ENBREL AFFORDABILITY REVIEW REPORT").

[9] This data comes from the Colorado All Payer Claims Database, which includes information from commercial insurers, Medicare Advantage, and Medicaid. ENBREL AFFORDABILITY REVIEW REPORT, at 2 & Appendix E.

[10] Immunex Corp. v. Sandoz, Inc., 395 F. Supp. 366, 379 (D.N.J. Aug. 9, 2019), aff'd 964 F.3d 1049 (Fed. Cir. 2020).

[11] CTRS. FOR MEDICARE & MEDICAID SERVS., MEDICARE DRUG PRICE NEGOTIATION PROGRAM: NEGOTIATED PRICES FOR INITIAL PRICE APPLICABILITY YEAR 2026 (2024).

[12] *Id.*

[13] ENBREL AFFORDABILITY REVIEW REPORT, at 2 (reporting that average out-of-pocket costs for Colorado patients with commercial insurance were $3,980 in 2022).

of drug pricing laws.[14] Several states have established affordability review boards, at least five of which authorize the boards to regulate maximum prices of prescription drugs within the state.[15] The Colorado legislature, for example, passed a law in 2021 creating the Colorado Prescription Drug Affordability Board.[16] The law authorizes the Board to conduct reviews of whether prescription drugs are unaffordable for Colorado consumers.[17] If the Board determines a drug is unaffordable, it can set an upper payment limit for the drug, which is the maximum amount that can be paid or billed for the drug if dispensed or distributed in Colorado.[18]

To date, the Board has declared three drugs unaffordable.[19] In 2024, Enbrel became the first drug that the Board found unaffordable.[20] The Board voted to set an upper payment limit for Enbrel in October 2025, which will go into effect in 2027.[21] The upper payment limit is similar to the price negotiated by CMS for Medicare.[22]

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[14] Nat. Acad. State Health Policy, State Laws Passed to Lower Prescription Drug Costs: 2017-2025, https://nashp.org/state-tracker/state-drug-pricing-laws-2017-2025/ (compiling state drug pricing laws, including affordability reviews, cost sharing limits, importation plans, and pharmacy benefit manager reform).

[15] Hannah-Alise Rogers, *Litigation Over State Attempts to Lower Drug Costs: Prescription Drug Affordability Boards*, Cong. Res. Serv. (Jan. 27, 2026) ("[A]t least five states (Colorado, Maryland, Minnesota, Washington, and Oregon) have authorized their PDABs to establish UPLs, which dictate the maximum price that can be paid or reimbursed for a drug by an in-state payer.")

[16] Legislative Declaration, Colorado Senate Bill 21-175.

[17] Colo. Rev. Stat. § 10-16-1406(2). The statute directs the Board to consider factors including wholesale acquisition costs, price increases, out-of-pocket costs, therapeutic class, impact on access, market competition, cost-effectiveness, and projected revenue, among other factors. *Id.* §§ 10-16-1406(1), 10-16-1406(4), 10-16-1406(6).

[18] Colo. Rev. Stat. § 10-16-1401(23).

[19] COLORADO PRESCRIPTION DRUG AFFORDABILITY BOARD, 2024 ACTIVITIES SUMMARY REPORT 6 (2025).

[20] 2024 SUMMARY REPORT, *supra* note 18, at 6.

[21] *See* Adopted UPL for Enbrel, https://doi.colorado.gov/types-of-insurance/health-insurance/prescription-drug-affordability-review-board.

[22] Hannah-Alise Rogers, *Litigation Over State Attempts to Lower Drug Costs: Prescription Drug Affordability Boards*, Cong. Res. Serv. (Jan. 27, 2026); Colorado Consumer Health Initiative, *Consumer Advocates Praise Prescription Drug Affordability Board's Decision to Set First-in-Nation Upper Payment*

Amgen, the manufacturer of Enbrel, has sued, challenging the constitutionality of the Board.[23] In a pending lawsuit, Amgen raises several constitutional challenges, including that the administrative structure violates due process and the dormant Commerce Clause.[24] One of its central arguments though is that federal patent law preempts the Colorado law under the Supremacy Clause.[25] This Article focuses on the federal preemption issues involved with the Colorado Prescription Drug Affordability Board and other similar efforts by state legislatures to regulate prescription drug prices.[26]

Under the Supremacy Clause of the Constitution, Congress can preempt state law by passing legislation that displaces state regulation.[27] Amgen's argument that federal patent law preempts Colorado's efforts to regulate drug prices relies heavily on a 2007 Federal Circuit case, *Biotechnology Industry Organization v. D.C.* ("*BIO v. DC*").[28] In that case, the Federal Circuit held federal patent law implicitly preempted a D.C. law that prohibited excessive pricing of patented drugs.[29] The *BIO v. DC* decision has been influential in the pharmaceutical industry, deterring states from regulating patented drug prices and providing ammunition for drug companies to challenge

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*Limit on the Expensive Drug Enbrel* (Oct. 3, 2025); *see also* Mot. for Preliminary Injunction 14-16, Amgen v. Mizner, Case No. 1:25-cv-3452 (D. Colo. 2025) (hereinafter "Amgen PI Motion").

[23] Compl., Amgen v. Mizner, Case No. 1:25-cv-3452 (D. Colo. 2025) (hereinafter "Amgen Complaint"). Amgen filed a prior lawsuit after the Board's determination that Enbrel was unaffordable. The district court dismissed the case due to lack of standing. Amgen, Inc. v. Mizner, 2025 WL 947474 (D. Colo. 2025). Amgen filed a second lawsuit after the Board voted on the upper payment limit, and then voluntarily dismissed a Federal Circuit appeal of the first lawsuit. *See* Amgen Inc. v. Colorado Pres. Drug Affordability Review Board, Docket 25-1641 (Fed. Cir.).

[24] Amgen Complaint, *supra* note 23.

[25] *Id.* at ¶¶ 100-09; Amgen PI Motion, *supra* note 22, at 25-30.

[26] Nat. Acad. for State Health Policy, *State Laws Passed to Lower Prescription Drug Costs: 2017-2025*, https://nashp.org/state-tracker/state-drug-pricing-laws-2017-2025/.

[27] *See infra* Part I.A.

[28] 496 F.3d 1362 (2007); Amgen Complaint, *supra* note 23, at ¶¶ 103-07, Amgen PI Motion, *supra* note 22, at 25-30.

[29] Biotechnology Indus. Org. v. D.C., 496 F.3d 1362, 1374 (Fed. Cir. 2007).

state reform efforts.[30] Scholars have argued that the result in *BIO v. DC* is bad policy and that the case does not control the outcome in the pending Colorado litigation.[31]

This Article contributes to this literature by adding an argument for why the Colorado law should not be preempted: *BIO v. DC* is inconsistent with Supreme Court precedent along several dimensions. In cases involving patent law, the pharmaceutical industry, and price regulation generally, the Supreme Court has consistently construed statutes narrowly to avoid preemption and refused to find preemption based on mere speculation about how a state law might impact federal goals. In contrast, the Federal Circuit interpreted the preemptive scope of patent law broadly, based on hypothetical concerns about how state laws might impact patent policy goals and broad inferences about congressional intent untethered to statutory text or affirmative federal regulation. Moreover, *BIO v. DC* is substantively inconsistent with Supreme Court precedent, which interprets federal law to allow states more leeway to regulate in ways that impact innovation policy goals, including with respect to access to medicine.

This Article contends that *BIO v. DC* is an example of exceptionalist decision-making for pharmaceutical patents and that such exceptionalism is misguided.[32] It therefore argues that *BIO v. DC* should be overruled. Although the Colorado law and similar state efforts can be distinguished from the D.C. law at issue in *BIO v. DC* because current laws do not single out patented drugs, the precedent will inevitably continue to create litigation costs for states so long as it is on the books.[33] If state price regulation is preempted only if state laws

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[30] *See* Amgen Complaint, *supra* note 23, at ¶¶ 103-07; Rebecca Wolitz, *States, Preemption, and Patented Drug Prices*, 52 SETON HALL L. REV. 385, 418 (2021) ("[*BIO v. DC*] has inspired states over the years to shift their focus in drafting excessive pricing laws to generics and inspired increased interest in payment regulation.").

[31] *See* Shweta Kumar, *Preempting Drug Price Reform*, WISC. L. REV. at 34-43 (forthcoming 2026) (arguing that the Colorado law is not, and should not be, preempted by distinguishing the Colorado law from the law at issue in *BIO v. DC*); Wolitz, *supra* note 30, at 385 (arguing that state drug price regulation should not be preempted by patent law).

[32] *See* Christopher Walker, *Chevron* Deference and Patent Exceptionalism, 65 DUKE L.J. 149, 149 (2016) (defining administrative law exceptionalism as "the misperception that a particular regulatory field is so different from the rest of the regulatory state that general administrative law principles do not apply").

[33] *See supra* note 28 and accompanying text.

target patented drugs, companies may argue that facially neutral laws regulating expensive drugs in practice target patented drugs, particularly since most expensive drugs are covered by patents.[34]

Highlighting the exceptionalist nature of the *BIO v. DC* decision is significant because the Supreme Court has shown interest in overruling Federal Circuit decisions when the Federal Circuit makes exceptionalist rules about generally applicable issues, such as standards of review of factual determinations, jurisdiction, and remedies.[35] Federal preemption is a trans-substantive issue that may similarly be a target for reversing the Federal Circuit's exceptionalist approach.[36] Moreover, although the dynamics of federal preemption can make outcomes difficult to predict based on politics,[37] timing may be ripe to reconsider a decision based on implied preemption rather than based on express statutory text, given that the Supreme Court has moved toward an overwhelmingly textualist approach to statutory interpretation.[38]

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[34] *See* ASPE OFFICE OF SCIENCE & DATA POLICY, ISSUE BRIEF: TRENDS IN PRESCRIPTION DRUG SPENDING 2016-2021 (SEPT. 2022) (reporting that brand name drugs, which are typically covered by patents, account for 80% of U.S. prescription drug spending). Indeed, Amgen has argued that the Colorado PDAB targeted its drug due to patent protection because the Board decided not to do an affordability review for a competing drug that had recently gone off patent. Mot. for Preliminary Injunction at 28-29.

[35] *See* Paul Gugliuzza & Mark Lemley, *Myths and Reality of Patent Law at the Supreme Court*, 104 B.U. L. REV. 891, 896 (2024) ("[T]he Federal Circuit does terribly in cases further removed from patent law substance, including on issues of jurisdiction and procedure, where the Supreme Court has agreed with it only once in 16 cases, and on questions of about remedies for patent infringement, where the Supreme Court has *never* agreed with the Federal Circuit."); Peter Lee, *The Supreme Assimilation of Patent Law*, 114 MICH. L. REV. 1413, 1416 (2016) (arguing that "the Supreme Court's recent patent jurisprudence reflects a project of eliminating 'patent exceptionalism' and assimilating patent doctrine to general legal principles"); *id.* at 1427-50.

[36] Gugliuzza & Lemley, *supra* note 35, at 898.

[37] Paul Gugliuzza, *Patent Trolls and Preemption*, 101 VA. L. REV. 1579, 1608 (2015).

[38] *See, e.g.*, Wyeth v. Levine, 129 S. Ct. 1187, 1211 (2009) (Thomas, J., concurring) ("This Court's entire body of 'purposes and objectives' pre-emption jurisprudence is inherently flawed. The cases improperly rely on legislative history, broad atextual notions of congressional purpose, and even congressional inaction in order to pre-empt state law.").

This Article proceeds in five parts. Part I provides background on federal preemption and the *BIO v. DC* decision. Part II argues that the *BIO v. DC* decision is inconsistent with Supreme Court precedent involving the preemptive scope of federal patent law. Part III argues that *BIO v. DC* is inconsistent with Supreme Court precedent involving preemption in the pharmaceutical industry generally. Part IV argues that *BIO v. DC* is inconsistent with Supreme Court precedent involving price regulation in other industries, particularly when there is no federal regulation of prices, as is the case for patented drugs. Part V contends that the inconsistency between the Federal Circuit's decision and Supreme Court precedent is problematic, then proposes reforms to align pharmaceutical patent preemption with the Court's general preemption jurisprudence.

## I. THE *BIO V. DC* DECISION

Federal law can preempt state law in several ways. This Part provides an overview of the general landscape of federal preemption, then summarizes the Federal Circuit decision that is central to this Article: *BIO v. DC*.

### *A. The General Preemption Framework*

Federal preemption derives from the Supremacy Clause of the Constitution, which provides that federal law "shall be the supreme Law of the Land."[39] Federal law can preempt state law either expressly or implicitly when a court concludes Congress intended to displace state law.[40] Implied preemption can arise either when federal law occupies an entire regulatory field or when a state law conflicts with federal law.[41] A state law may conflict with federal law when it is impossible to comply with both federal and state regulations or when the state law poses an obstacle to accomplishing federal goals.[42] Patent laws do not

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[39] U.S. Const., art. VI, cl. 2.

[40] Bryan Adkins, Alexander Pepper, & Jay Sykes, *Federal Preemption: A Legal Primer*, Cong. Res. Serv. R45825 (2023).

[41] Adkins et al., *supra* note 40, at 2.

[42] Adkins et al., *supra* note 40, at 2-3 & Fig. 1; *see also* Wyeth v. Levine, 129 S. Ct. 1187, 1196-1204 (2009) (considering claims under theories of both obstacle and impossibility preemption); Kewanee Oil Co. v. Bicron, 416 U.S. 470, 479-80 (1974) (describing the legal test for obstacle preemption, which

contain an express preemption clause.[43] Therefore, preemption cases based on federal patent law are based on theories of implied preemption, typically under the theory of obstacle preemption.[44]

In general, the guiding inquiry in federal preemption is whether Congress intended to preempt state law, focusing primarily on statutory text.[45] Out of respect for the sovereignty of states as independent governments, the Court has taken the view that statutes should be construed narrowly to avoid preemption of state regulation.[46] When states regulate accordingly to their traditional police powers to protect public health, safety, and welfare, the Court applies a presumption that state law is not preempted.[47] State police power regulations are therefore typically not preempted unless a court concludes preemption was the "clear and manifest purpose of Congress."[48]

### *B. The Federal Circuit Opinion*

In *BIO v. DC*, the Federal Circuit considered a D.C. law that made it unlawful for drug manufacturers to sell patented prescription drugs in the District at "excessive" prices.[49] Although D.C. laws are technically federal law, the same principles of preemption that apply between state law and federal law also apply between D.C. laws and

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considers whether a state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress").

[43] Camilla Hrdy, *Getting Patent Preemption Right*, J. INTELL. PROP. L. 307, 320 (2017).

[44] *See, e.g.*, Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470, 479-80 (1974) (analyzing whether state trade secret law posed an obstacle to federal patent goals because "patent law does not explicitly endorse or forbid the operation of trade secret law.").

[45] Adkins et al., *supra* note 40, at 3; *see also* Morales v. Trans World Airlines, 504 U.S. 374, 383 (1992) ("The [preemption] question, at bottom, is one of statutory intent.").

[46] *See* Medtronic, Inc. v. Lohr, 518 U.S. 470, 485 (1996).

[47] Wyeth v. Levine, 129 S. Ct. 1187, 1195 (2009).

[48] *Wyeth*, 129 S. Ct. at 1195 (quoting *Lohr*, 518 U.S. at 485).

[49] 496 F.3d 1362 (Fed. Cir. 2007). Under the law, a prima facie case of excessive price was established if a price was at least 30% higher than in certain other high income countries. *Id.* at 1365. A drug company could rebut a prima facie case of excessive pricing with evidence of costs, profits, government support, and impacts on access. *Id.*

laws passed by Congress.[50] Therefore, the court applied preemption principles from cases involving challenges to state regulations, and the decision created precedent for future state regulations beyond D.C.

The Federal Circuit held that the D.C. excessive price law was preempted by patent law under a theory of obstacle preemption.[51] In an opinion written by Judge Gajarsa, the court reasoned that the fundamental goal of patent law is to encourage innovation.[52] Pointing to Federal Circuit precedent, the court emphasized that the ability of patent holders to earn "above-market profits" plays a central role in creating an incentive for parties to invest in research and development of new technologies.[53] It then stated that Congress also had acknowledged the "central role of enhanced profits," pointing exclusively to legislative history from the Hatch-Waxman Act.[54]

The Hatch-Waxman Act governs the FDA approval process for generic versions of prescription drugs. The law includes a mix of provisions that relate to FDA law and patent law. In an effort to increase generic drug competition, and thereby *lower* drug prices, Congress created an expedited approval pathway for generic drugs.[55] Rather than conduct clinical trials, as brand drugs must do for initial approval, a generic can obtain FDA approval by merely showing that the drug is bioequivalent to a brand drug product.[56]

Yet at the same time that Congress sought to facilitate generic entry into the prescription drug market, it recognized that increased generic competition may reduce incentives for brand manufacturers to develop new drugs in the first place.[57] To guard against concerns about the reduction in innovation incentives for brand manufacturers, the law also included provisions that allow drug companies to extend the patent term of one patent covering an FDA-approved drug and that create market exclusivities that govern when generic companies may begin

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[50] *Id.* at 1371.

[51] *BIO v. DC*, 496 F.3d at 1372-74.

[52] *Id.* at 1372.

[53] *Id.* at 1372-73.

[54] *Id.* at 1373.

[55] Wolitz, *supra* note 30, at 437-38; Kevin Hickey & Erin Ward, *The Role of Patents and Regulatory Exclusivities in Drug Pricing*, Cong. Res. Serv. R46679 9-10 (2024).

[56] Wolitz, *supra* note 30, at 438; Hickey & Ward, *supra* note 55, at 9-10.

[57] Wolitz, *supra* note 30, at 437-38; Hickey & Ward, *supra* note 55, at 29-30.

seeking FDA approval.[58] Once a generic files for FDA approval, the Hatch-Waxman Act also provides a set of specialized procedures for litigating disputes about patent infringement.[59]

In *BIO v. DC*, the Federal Circuit pointed to two statements in the legislative history discussing the portion of the Hatch-Waxman Act that created patent term extension.[60] It quoted a statement from the House Committee Report that patents "enable innovators to obtain greater profits than could have been obtained if direct competition existed" and that those profits "act as incentives for innovative activities."[61] Based on the premise that increased financial rewards are central to the goals of patent law, the Federal Circuit concluded that the D.C. excessive price law impermissibly interfered with the goals of patent law.[62] In the court's view, because the D.C. law "in effect diminish[ed] the reward to patentees," it sought to "change federal patent policy" within the District.[63] The court concluded that the decision about "the proper balance between innovators' profit and consumer access to medication" is exclusively reserved for Congress.[64] The D.C. law, therefore, stood as an obstacle to the objectives of federal patent law and was preempted.[65]

After the panel opinion issued, the Federal Circuit denied a petition for rehearing en banc.[66] Judge Gajarsa wrote a concurring opinion, reiterating the reasoning of the panel opinion.[67] Judge Dyk dissented.[68] Among other objections, Judge Dyk wrote that the panel opinion was "inconsistent with longstanding Supreme Court precedent," citing several Supreme Court cases regarding the scope of federal patent rights.[69]

This Article argues that the *BIO v. DC* opinion is inconsistent with Supreme Court precedent in even more ways than Judge Dyk's

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[58] Wolitz, *supra* note 30, at 437.

[59] Hickey & Ward, *supra* note 55, at 29-35.

[60] *BIO v. DC*, 496 F.3d at 1373.

[61] *Id.* at 1373 (quoting H.R. Rep. No. 98-857, at 17 (1984)).

[62] *Id.* at 1374.

[63] *Id.*

[64] *Id.*

[65] *Id.*

[66] Biotechnology Industry Org. v. D.C., 505 F.3d 1343, 1344 (Fed. Cir. 2007) (denial of petition for rehearing en banc).

[67] *Id.* at 1346-47.

[68] *Id.* at 1348-51 (Dyk, J., dissenting from denial of rehearing en banc).

[69] *Id.* at 1350.

opinion suggests, based on both longstanding Supreme Court precedent and Supreme Court cases decided since the Federal Circuit opinion in 2007. In the following Parts, this Article provides a comprehensive analysis of ways that the *BIO v. DC* opinion is inconsistent with Supreme Court precedent based on cases involving patent law, the pharmaceutical industry, and price regulation. It highlights both substantive inconsistencies, such as about the scope of patent rights and judgments reserved to Congress, as well as inconsistencies in approaches to the preemption analysis.

## II. EXCEPTIONALISM WITHIN PATENT LAW

Federal patent law authorizes the U.S. Patent and Trademark Office to grant patents on new, nonobvious, and useful inventions that are adequately described in a patent application.[70] A patent gives the patent holder the right to exclude others from making, using, selling, and importing the patented invention for a limited period of time, usually around twenty years.[71] Patent laws do not expressly preempt any state laws.[72]

Supreme Court precedent regarding the preemptive scope of federal patent law is consistent with its generally narrow approach to implied preemption. The contexts where the Supreme Court has found state law preempted involve situations where Congress has made an affirmative judgment about what information should be in the public domain, such as by defining patentability standards and patent terms.[73] When state laws conflict with that affirmative judgment by providing exclusive rights over information in the public domain, the Court has held that state laws are preempted.[74] Yet in other contexts, the Court has been reluctant to find that patent law preempts state regulation. It has upheld state power to regulate in ways that do not directly affect patent rights or that only place a reasonable burden on them.[75] Moreover, the Court has been reluctant to find preemption based on speculation that state laws will undermine patent policy goals.[76]

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[70] 35 U.S.C. §§ 101, 102, 103, 112.
[71] *Id*. §§ 154, 271.
[72] Hrdy, *supra*, note 43, at 320.
[73] *See infra* Part II.B.
[74] *See infra* Part II.B.
[75] *See infra* Part II.
[76] *See infra* Part II.A.

This Part describes Supreme Court precedent involving the preemptive scope of federal patent law, which primarily focuses on two categories of state laws: laws that regulate patent holder activities and laws that impact patent policy goals. It argues that the *BIO v. DC* decision is inconsistent with Supreme Court precedent in both categories.

### *A. Regulation of Patent Holder Activities*

The Supreme Court has generally held that states retain broad power to regulate patent holder activities pursuant to their traditional police powers. Just as states can regulate the sales of physical property generally, states can regulate the sales of patented products.[77] Furthermore, states have broad power to regulate commercial transactions, including transactions involving patents.[78] To analyze the scope of state power, the Court has considered whether a state regulation directly interferes with patent rights and if so, whether it places an unreasonable burden on those rights. The *BIO v. DC* opinion diverges from this approach by taking an exceptionally broad view of what rights attach to patents and by considering any burden on patent rights to be sufficient for preemption.

#### 1. Sales of Patented Products

States have long had power to regulate the use of property within their borders.[79] When a patent holder seeks to sell a patented product, Supreme Court precedent has long held that states have the same power to regulate the use of patented products as they do to regulate the use of tangible property generally.[80] Patent law grants the patent holder a right to exclude, but it does not provide an affirmative right to make, use, or sell the invention. A patent on a new type of firework, for example, would not entitle the patent holder to sell it in every state.[81] Because patent law merely provides a right to exclude

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[77] *See infra* Part II.A.1.

[78] *See infra* Part II.A.2.

[79] *See, e.g.*, Lucas v. S.C. Coastal Council, 505 U.S. 1003, 1027-29 (1992) (describing traditional state powers to regulate property to abate nuisances and states' "traditionally high degree of control over commercial dealings"); Mugler v. Kansas, 123 U.S. 623 (1887) (explaining that all property is held subject to state police power regulations).

[80] Patterson v. Kentucky, 97 U.S. 501 (1878).

[81] Thanks to Mike Burstein for this example.

others, state regulations of the sale, use, or manufacture of *physical* property (such as bans on sales of fireworks) do not interfere with patent rights. These regulations have no impact on whether the patent holder can exclude *others* from using the patented invention, which is what federal patent law regulates. States are free to regulate physical property pursuant to their traditional police powers, which broadly allow states to regulate to promote public health and welfare.[82] Although state regulation of physical property is subject to other constitutional limits, such as the dormant Commerce Clause and the Takings Clause, federal patent law does not preempt state regulation of physical property.[83]

In *Patterson v. Kentucky*, for example, the Supreme Court held that a state law prohibiting the sale of patented products was not preempted by patent law.[84] In that case, the patent holder obtained a patent on burning oil used to produce light in devices such as lamps.[85] A Kentucky statute only allowed burning oil that met certain safety standards to be sold within the state for illuminating purposes.[86] The patented oil did not meet the Kentucky statute's safety requirements, and the patent holder was fined for selling the patented oil in Kentucky.[87] The Court held that federal patent law did not preempt the Kentucky law because a patent merely provides a right to exclude, not an affirmative right to sell the patented invention.[88] A patent holder's rights in physical objects are distinct from the rights granted in the patent to exclude others from making and using the patented

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[82] *See, e.g.*, William Michael Treanor, *The Original Understanding of the Takings Clause and the Political Process*, 95 COLUM. L. REV. 782, 797 & n.81 (1995) (describing cases where the Supreme Court concluded that state regulations were valid exercises of state police powers, and accordingly were not takings).

[83] State actions that violate the dormant Commerce Clause are invalid. *See, e.g.*, Philadelphia v. New Jersey, 437 U.S. 617 (1978). State actions that are takings require just compensation but the action can still be taken. *See* West River Bridge Co. v. Dix, 47 U.S. (6 How) 507, 532 (1848) (observing that all property is held subject to the state's eminent domain power).

[84] 97 U.S. 501 (1878).

[85] *Patterson*, 97 U.S. at 502.

[86] *Id.*

[87] *Id.* ("[T]he Aurora oil could not, by any chemical combination described in the patent, be made to conform to the standard or test required by the Kentucky statute as a perquisite to the right, within that State, to sell, or to offer for sale, illuminating oils of the kind designated.").

[88] *Id.* at 506.

invention.[89] With respect to physical objects, patented products remain subject to regulations issued under state police powers to promote public health and welfare. Because the law regulating the sale of burning oil within the state was a valid exercise of Kentucky's police powers, the existence of a patent did not exempt the patent holder from the state regulation.[90]

Similarly, in *Webber v. Virginia*, the Supreme Court held that federal patent law did not preempt state laws requiring licenses and taxes to sell products, including patented products, within the state.[91] In that case, a Virginia law required sewing machines manufacturers to obtain a license and pay a tax before selling sewing machines within the state. The Court held that the existence of a patent on a particular sewing machine did not exempt the patent holder from complying with the state licensing and tax requirements.[92] Agreeing with the reasoning of *Patterson*, the Court explained that Congress did not intend for patent laws to displace state police powers over tangible property within their borders.[93] It provided other examples: a patent on a dynamite powder or a deadly poison would not prevent a state from regulating the manufacture, storage, and sale of those products within the state.[94]

### 2. Transactions Involving Patents

State regulations of patented products do not directly impact any patent rights themselves; patents provide no affirmative rights to sell the patented invention. Yet even when a state regulation impacts a patent right directly, the Supreme Court has still allowed some room for state regulation. Just as states have traditionally had broad power to regulate property within their borders, states have also traditionally had broad power to regulate contracts and commercial transactions.

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[89] *Id.*

[90] *Id.* at 506-08.

[91] 103 U.S. 344, 347 (1880).

[92] *Webber*, 103 U.S. at 347-49 ("[W]e can find no objection to the legislation of Virginia in requiring a license for the sale of the sewing-machines, by reason of the grant of letters-patent for the invention.").

[93] *Id.* at 347-48.

[94] *Id.* at 347. The Court separately, however, addressed a dormant Commerce Clause challenge and concluded the Virginia law impermissibly discriminated against out-of-state manufacturers.

Pursuant to these powers, the Supreme Court has upheld state regulation of transactions specifically involving patents.

In *Allen v. Riley*, the Supreme Court held that states have power to make reasonable regulations to deter fraudulent transfers of patents, even though federal patent law provides that ownership of patents can be transferred to another entity through written agreements.[95] In that case, the state of Kansas passed a law requiring that before a patent could be transferred within the state, a patent holder had to file an authenticated copy of the patent and an affidavit swearing that the holder had authority to transfer the patent.[96] Because the statute was a "reasonable and fair exercise" of the state's power to protect its residents from fraudulent transactions, it was not preempted by patent law.[97] Although the Court doubted that a state could totally prohibit all transfers of patents, it concluded that the Kansas law did not create an unreasonable burden on the ability to transfer a patent.[98] Although the filing requirement added steps required to sell a patent, the requirement was not, in the Court's view, inconsistent with the federal statute authorizing written transfers of patents.[99] In the absence of express legislation preempting state regulation, the Court concluded that patent law did not take away the ability of states to regulate to prevent fraud.[100]

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[95] 203 U.S. 347, 355-56 (1906) ("[T]he case before us relates to provisions which are to accompany an assignment of intangible rights, growing out of a patent, yet the general power of the states to legislate in order to protect their citizens in their lives and property from fraud and deceit is recognized.").

[96] *Allen*, 203 U.S. at 350.

[97] *Id.* at 356.

[98] *Id.* at 355-57 ("The expense of filing copies of the patent and the making of affidavits in the various counties of the state in which the owner of the rights desired to deal with them is not so great, in our judgment, as to be regarded as oppressive or unreasonable.").

[99] *Id.* at 357.

[100] *Id.* More recently, states have passed laws aimed at curbing bad faith assertions of patent infringement, sometimes referred to as "anti-patent-troll laws." *See* Camilla Hrdy, *The Reemergence of State Anti-Patent Law*, 89 U. COLO. L. REV. 133, 135-36 (2018). In a similar context, the Federal Circuit has rejected obstacle preemption challenges to state unfair competition claims based on bad faith patent assertions. *See* Dow Chemical Co. v. Exxon Corp., 139 F.3d 1470, 1473-79 (Fed. Cir. 1998).

3. Pharmaceutical Patent Exceptionalism

Under the approach discussed above, the Supreme Court has considered whether a state regulation directly interferes with patent rights granted by Congress and if so, whether it places an unreasonable burden on those rights to determine whether federal patent law preempts state regulation. The approach is narrow, leaving states with broad discretion to regulate pursuant to their traditional police powers. The *BIO v. DC* opinion diverges from this approach, creating an exceptionalist rule that limits state power over patented drugs more than state power is limited over other patented products and even over transactions involving patents.

One significant way that the *BIO v. DC* is substantively inconsistent with the Supreme Court's approach is that the Federal Circuit defined the scope of the patent right as much broader than Supreme Court cases. In *BIO v. DC*, the court stated that the D.C. law limited the "full exercise of exclusionary power that derives from a patent" by "penalizing high prices."[101] Yet regulating the price that a patentee can sell a product for has no impact on the separate right to exclude conferred by a patent.[102] Just like the state laws at issue in *Patterson* and *Webber*, the D.C. law had no impact on the right to exclude—it did not authorize any generic competitors to enter the

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[101] *BIO v. DC*, 496 F.3d at 1374.

[102] Indeed, in the context of patent exhaustion, the Supreme Court has stated that "the Patent Act does not guarantee a particular price." Impression Prods., Inc. v. Lexmark Int'l, Inc., 581 U.S. 1523, 1528 (2017). Antitrust law also illustrates that patents do not confer a right to charge unregulated prices. At the federal level, patents do not provide blanket immunity from antitrust regulation, including pharmaceutical patents. *See* FTC v. Actavis, 570 U.S. 136 (2013) (holding that patent settlement agreements between pharmaceutical companies in Hatch-Waxman litigation are subject to antitrust scrutiny). As Judge Dyk observed in his dissent, patents do not confer special rights on patent holders to fix prices when they sell patented products. *See* BIO v. DC., 505 F.3d 1343, 1350 (Fed. Cir. 2007) (Dyk. J., dissenting from the denial of rehearing en banc) (citing United States v. Gen. Elec. Co., 272 U.S. 476, 493-94 (1926)); *see also* Sola Elec. Co. v. Jefferson Elec. Co., 317 U.S. 172, 173-77 (1942) (holding that licensee estoppel did not prevent a patent licensee from challenging a patent license that included a price-fixing clause under federal antitrust laws). Furthermore, the Supreme Court has held that states may tax royalties earned from patent licenses, further casting doubt on the idea that a patent confers a right to earn unregulated profits. *See* Fox Film Corp. v. Doyal, 286 U.S. 123, 130-31 (1932).

market or impose any limits on patent licensing and assertion.[103] The state laws at issue in *Patterson* and *Webber* would have undoubtedly impacted the financial rewards that patent holders could recoup.[104] By prohibiting the sale of patented oil altogether, the law in *Patterson* eliminated the patent holder's ability to earn any financial rewards within the state.[105] Moreover, the licensing and tax requirements in *Webber* increased the costs of selling patented sewing machines within the state, which in turn, could have predictably impacted the financial rewards for patent holders.[106]

In both *Patterson* and *Webber*, the Supreme Court held that patents posed no barrier to state regulation of sales of patented products.[107] Because the states acted within the scope of their police powers in both situations, the state regulations were valid.[108] The D.C. law similarly seemed to fall comfortably within traditional state police powers. It sought to promote public health and welfare by addressing concerns about the affordability of medicine and economic harms to the District.[109] There was no suggestion that the law was outside the scope of D.C.'s police power. Following Supreme Court precedent then, the D.C. law should have been a valid state regulation of patented products. Yet in *BIO v. DC*, the Federal Circuit diverged from this approach by extending the scope of federal patent preemption to cover a regulation about the sale of patented products.[110]

The *BIO v. DC* decision therefore seems to rest on an assumption that pharmaceutical patents are different than other types of patents. But there is no principled reason for treating pharmaceutical patents differently from other patents, such as those covering sewing machines and burning oil. Just as patents generally do not create an affirmative right to make, sell, or use the patented invention, pharmaceutical patents do not create an affirmative right to make, use, or sell patented

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[103] *See supra* Part II.A.1.

[104] *See supra* Part II.A.1.

[105] Patterson v. Kentucky, 97 U.S. 501, 506-08 (1878).

[106] Webber v. Virginia, 103 U.S. 344, 347 (1880).

[107] *See supra* Part II.A.1.

[108] *See supra* Part II.A.1.

[109] *BIO v. DC*, 496 F.3d at 1365.

[110] *Id.* at 1374; *see also* Biotechnology Industry Org. v. D.C., 505 F.3d 1343, 1350 (Fed. Cir. 2007) (Dyk. J., dissenting from the denial of rehearing en banc) ("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.").

drugs. Drug manufacturers must obtain FDA approval before they can sell drugs in interstate commerce.[111]

The Hatch-Waxman Act, which the Federal Circuit discusses, does make pharmaceutical patents different from other patents in some respects. For example, patent term extension is available for one patent covering an FDA-approved product.[112] The Hatch-Waxman Act also includes provisions that effectively guarantee injunctions as remedies if a court concludes that a generic drug manufacturer infringes certain types of pharmaceutical patents.[113] These provisions, do not, however create any affirmative right to sell patented drugs or entitle drug companies to earn a certain level of profits.[114] Instead, they simply extend and strengthen the exclusivity period for patents covering FDA-approved products.[115] These provisions deal with the right to exclude competitors, but have no bearing on affirmative rights to sell drugs at particular prices or even to sell drugs at all.

Notably, Congress did not choose to encourage pharmaceutical innovation by guaranteeing a particular level of profits—instead, it continued the general patent law model of encouraging innovation by providing a right to exclude competitors for a limited period of time. The Hatch-Waxman Act legislative history, cited in *BIO v. DC*, confirms this view. The House Committee Report quoted in the opinion states that "[p]atents…enable innovators to obtain greater profits than could have been obtained *if direct competition existed*."[116] Through the Hatch Waxman Act, Congress continued the same structure that exists in

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[111] *See* 21 U.S.C. § 355(a).

[112] 35 U.S.C. § 156.

[113] The Hatch-Waxman Act requires companies to list patents covering FDA-approved drugs and methods of using that drug in the Orange Book. When a generic manufacturer files for FDA approval, the brand manufacturer can sue the generic for infringing patents listed in the Orange Book. If the patent holder timely sues, the law provides that the FDA cannot approve the generic application for at least 30 months, and the FDA cannot approve a generic application until after Orange Book patents expires if a court finds those patents infringed. *See* 21 U.S.C. § 355(b)(1), 355(j)(5)(B)(iii); 35 U.S.C. § 271(e)(4).

[114] *See* Wolitz, *supra* note 30, at 437.

[115] 35 U.S.C. § 156.

[116] 496 F.3d at 1373 (quoting H.R. Rep. No. 98-857, at 17 (1984) (emphasis added); *see also* BIO v. DC 505 F.3d 1343, 1346 (Fed. Cir. 2007) (Gajarsa, J., concurring in the denial of rehearing en banc) (quoting additional legislative history describing the ability to exclude generic competition as an innovation incentive).

other contexts: the right to exclude direct competitors provides an opportunity to earn greater profits, in turn, providing an incentive to invest in research and development.[117] It does not, however, entitle patent holders to particular levels of profits or immunize them from state police power regulation of physical property. All markets inevitably include regulations that impact the profits a patent holder can earn by selling patented products.

Allowing drug companies to enjoy longer periods of exclusivity can allow them to earn greater profits than they would if they faced direct competition, even if some form of price regulation is imposed on patented drugs. The Medicare Drug Price Negotiation Program provides an example of this. Drugs are only eligible for price negotiation if they do not face competition after a certain period of time.[118] Drug companies, therefore, could avoid price negotiation by licensing their patents and allowing just one generic competitor to enter the market.[119] Studies have shown that generic prices are often steeply discounted compared to prices charged when a brand drug does not face competition, and brand manufacturers can lose significant amounts of market share after generic competitors enter the market.[120] Given these market dynamics, scholars have predicted that brand drug manufacturers in certain circumstances may be more likely to continue excluding generics and enter into Medicare price negotiations.[121] When the expected profit loss from Medicare price negotiation would be less than the expected profit loss from generic competition, brand drug companies may still earn more money through excluding generics, even

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[117] *See* BIO v. DC, 505 F.3d 1343, 1351 (Fed. Cir. 2007) (Dyk. J., dissenting from the denial of rehearing en banc) ("A law that does nothing to interfere with exclusivity also does nothing to interfere with [the purpose of the Hatch-Waxman Act].").

[118] *See* 42 U.S.C. § 1320f-1(e) (defining "qualifying single source drug" as one that is not the reference product for a generic small molecule drug or a biosimilar).

[119] Arti Rai, Rachel Sachs, & Nicholson Price, *Cryptic Patent Reform Through the Inflation Reduction Act*, 37 HARV. J. L. & TECH. 57, 62 (2023) (discussing how the prospect of Medicare price negotiation may lead drug companies to license patents and avoid negotiation).

[120] Rai, Sachs, & Price, *supra* note 119, at 74-75 (describing studies finding that the average price of a generic was 39% lower than a branded drug when one generic competitor entered the market and showing branded firm market share dropped to 23% after one year of generic competition).

[121] Rai, Sachs, & Price, *supra* note 119, at 75.

with some level of price regulation.[122] Therefore, price regulation and market exclusivity can be a combination that still provides greater financial rewards for drug manufacturers than a market with direct competition.

One counterargument is that *BIO v. DC* is consistent with Supreme Court precedent discussed above because unlike the state laws at issue in *Patterson* and *Webber*, the D.C. law only applied to patented products specifically.[123] The laws in *Patterson* and *Webber*, on the other hand, applied to classes of products generally, such as all burning oils and all sewing machines, whether they were patented or not.[124] Judge Gajarsa emphasized this feature of the D.C. law.[125] He cited *Webber*, observing that the Supreme Court stated that the sale of patented articles "cannot be forbidden by the State, except as the production and sale of other articles, for the manufacture of which no invention or discovery is patented or claimed, may be forbidden."[126]

Taken out of context, this language seems to suggest that a state cannot single out patented products for regulation. Yet in the context of the full opinion, a better reading is that States have the same power to regulate patented products as they do to regulate unpatented products.[127] The next paragraph goes on to explain that a patent does not prevent a State from regulating the manufacture, storage, and sale of dynamite power "to protect the community from the danger of explosion" nor does a patent "lessen the right of the State to control [the] handling and use" of a deadly poison.[128] Congress did not intend for patent law to "displace the police power of the States," which refers to the States' power to regulate to promote "health, good order, peace, and general welfare" of the community.[129] Whatever rights that patents

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[122] Rai, Sachs, & Price, *supra* note 119, at 74-82 (predicting that Medicare price negotiation will be unlikely to impact patent assertion strategies for small molecule drugs, though not for biologics due to different market dynamics).

[123] *See* Part II.A.1.

[124] *See* Part II.A.1.

[125] *BIO v. DC*, 496 F.3d at 1374 ("The fact that the Act is targeted at the patent right is apparent on its face. It applies only to patented drugs.").

[126] *Id.* (quoting Webber v. Virginia, 103 U.S. 344, 347 (1888)).

[127] Webber v. Virginia, 103 U.S. 344, 347 (1888) ("The legislation respecting articles which the State may adopt after the patents have expired, it may equally adopt during their continuance.").

[128] *Webber*, 103 U.S. at 347.

[129] *Id.* at 347-48.

"secure[] to inventors," the Court held, "must be enjoyed in subordination to this general authority of the State over *all property* within its limits."[130] In *Webber*, there was no objection that the licensing requirements for sewing machines were outside the State's police powers.[131] Instead, the argument was that a patent exempted the patent holders from state police power regulations. The discussion in *Webber*, therefore, is best understood as explaining that patented products are subject to regulation under state's police powers, just as all property is.

The Supreme Court's decision in *Allen* reinforces this understanding of *Webber* as well, where the Court held that a state law regulating transfers of patents specifically was not preempted.[132] That state law directly targeted patent rights—it aimed to reduce fraudulent transactions involving patents, and it limited the right to transfer patents granted by the federal law.[133] Yet still, the Court held that it was not preempted because it did not place an unreasonable burden on the right to assign patents.[134] In contrast, the Federal Circuit did not even consider how much of a burden the D.C. law placed on patent rights, perhaps because it placed no burden on patent rights themselves.

Therefore, the discussion in *Webber* does not suggest that States cannot regulate patented products specifically. Instead, it instructs that States can regulate patented products to the same extent that they can regulate all property. The appropriate constitutional question, therefore, should be whether the state law is a valid exercise of the State's police powers (and whether it violates any other constitutional provisions, such as a dormant Commerce Clause)—not whether federal patent law preempts the state action. These are distinct constitutional challenges to state action from preemption.[135] The *BIO v. DC* opinion unjustifiably departed from this approach by assuming that regulations

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[130] *Id.* at 348.

[131] *Id.* at 349 (observing that there was, however, an objection under the dormant Commerce Clause).

[132] *See supra* Part II.A.2.

[133] *See supra* Part II.A.2.

[134] *See supra* Part II.A.2.

[135] Given the breadth of state police powers to promote public health and welfare, it is unlikely that the D.C. law was outside the scope of the District's police powers. *See* Kumar, *supra* note 31, at 38; BIO v. DC, 505 F.3d 1343, 1351 (Fed. Cir. 2007) (Dyk. J., dissenting from the denial of rehearing en banc).

of patented drugs are different from regulations of other patented products, even though federal law does not support such a distinction.

### *B. Regulations Impacting Patent Policy Goals*

Beyond considering cases involving state regulation of patent holder activities, the Supreme Court has also considered cases involving state regulation that impacts patent policy goals without regulating patent holder activities directly. Examples of state laws in this category include trade secret laws and regulation of exclusive rights over unpatented ideas. Throughout these cases, the Supreme Court has considered whether state laws pose obstacles to three primary goals of federal patent policy: promoting innovation, encouraging disclosure of information about inventions, and allowing free access to information in the public domain. Analyzing these goals, the Court has allowed states to regulate in ways that have some impact on patent policy goals, refusing to find state laws preempted based on speculation that the state laws might undermine patent policy goals. In *BIO v. DC*, the Federal Circuit diverged from this approach by finding preemption based on speculation about the impact of the D.C. law on patent policy goals, without considering the extent of the impact or how the law might be applied.

#### 1. Exclusive Rights Over Inventions

Federal patent law generally preempts state efforts to grant exclusive rights over publicly available information.[136] The Supreme Court has explained that in creating patent laws, Congress struck a compromise between two competing innovation policy goals.[137] On the one hand, allowing free competition in unpatented ideas promotes a competitive economy and further innovation.[138] On the other hand, allowing limited exclusive rights over inventions can encourage development of the inventions in the first place and encourage inventors to publicly disclose information, which can later be used by

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[136] Bonito Boats, Inc. v. Thunder Craft Boats, Inc., 489 U.S. 141, 156 (1989) ("[T]he States may not offer patent-like protection to intellectual creations which would otherwise remain unprotected as a matter of federal law."). This refers specifically to information that could be subject to patent protection, such as functional attributes of inventions. *Id.* at 164-65.

[137] *Bonito Boats*, 489 U.S. at 144.

[138] *Id.* at 148.

others to further innovate.[139] Based on this balance struck by Congress, the Supreme Court has held that federal patent law is the exclusive means for a party to obtain rights to exclude others from using publicly available information regarding inventions that are potentially patentable.[140] State laws providing exclusive rights over publicly available information, in turn, are typically preempted by patent law because they conflict with federal goals.

The Supreme Court precedent, for example, instructs that states may not provide exclusive rights over the subject matter of a patent after the patent expires.[141] Similarly, the Supreme Court has held that patent law provides the public the right to use public information freely when an invention does not meet the federal standards for patentability.[142] In *Bonito Boats, Inc. v. Thunder Craft Boats*, the Court held that a Florida law that prohibited copying information in the public domain without permission was preempted by patent law.[143] The law specifically made it unlawful to duplicate and sell certain parts of boats without any time limit or any regard to whether the boat parts

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[139] *Id*. at 150-51 ("The federal patent system thus embodies a carefully crafted bargain for encouraging the creation and disclosure of new, useful, and nonobvious advances in technology and design in return for the exclusive right to practice the invention for a period of years.").

[140] *Id*. at 149 ("Once an inventor has decided to lift the veil of secrecy from his work, he must choose the protection of a federal patent or the dedication of his idea to the public at large.").

[141] *See* Coats v. Merrick Thread Co., 149 U.S. 562, 572 (1893) ("[P]laintiffs' right to the use of the embossed periphery expired with their patent, and the public had the same right to make use of it as if it had never been patented."); Kellogg Co. v. National Biscuit Co., 305 U.S. 111, 117-18 (1938) (holding that upon patent expiration, "there passed to the public … the right to make the article as it was made during the patent period"); Singer Mfg. Co. v. June Mfg. Co., 163 U.S. 169, 185 (1896) ("It is self-evident that on the expiration of a patent the monopoly created by it ceases to exist, and the right to make the thing formerly covered by the patent becomes public property."); *see also* Brulotte v. Thys Co, 379 US 29 (1964) (holding that a patent license agreement that requires royalties after patent expiration is unlawful per se).

[142] *Bonito Boats*, 489 U.S. at 151 ("State law protection for techniques and designs that have already been induced by market rewards may conflict with the very purpose of the patent laws by decreasing the range of ideas available as the building blocks of further innovation.").

[143] 489 U.S. 141, 144-45 (1989).

met the federal criteria for patentability.[144] The Court reasoned that the federal requirements for patentability reflected Congress's judgment about the best way to promote innovation.[145] Specifically, by requiring that an invention be novel and nonobvious to obtain patent protection, Congress decided to deny exclusive rights over information that is already publicly known or could be "readily discerned from publicly available material."[146] In doing so, Congress allowed the public to use existing information in the public domain to further innovate and provided an incentive for inventors to meet the rigorous patentability requirements.[147]

The Court therefore concluded that state laws that interfere with public use of potentially patentable ideas that have been publicly disclosed were preempted because they undermine the goals of the patent system.[148] The Court applied similar reasoning to contexts involving invalid patents. In *Sears, Roebuck & Co. v. Stiffel*, the Court held that state unfair competition law cannot impose liability merely for copying a product that was the subject of an invalid patent.[149] Although state unfair competition law may seek to protect consumers from being misled, the Court concluded that it cannot create liability for the mere use of information in the public domain.[150]

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[144] It applied to direct molding processes used to manufacture boat hulls, which are bodies of ships, or component parts of boats. *Bonito Boats*, 489 U.S. at 144-45, 148-50.

[145] *Bonito Boats*, 489 U.S. at 148-50.

[146] *Id.* at 150.

[147] *See id.* at 160-61 (describing how the Florida law could undermine these objectives); *id.* at 164-65 (concluding that federal patent laws create a "federal right to 'copy and to use'" information in the public domain).

[148] *Id.* at 159-60 ("We think it clear that such protection conflicts with federal policy 'that all ideas in general circulation be dedicated to the common good unless they are protected by a valid patent.'") (citing Lear, Inc. v. Adkins, 395 U.S. 653, 668 (1969)); *id.* at 167 (holding that the Florida law "enters a field of regulation which the patent laws have reserved to Congress").

[149] 376 U.S. 225 (1964); *see also* Compco Corp. v. Day-Brite Lighting, Inc., 376 U.S. 234, 237-38 (1964) (reaching the same conclusion for state unfair competition claim based on copying design claimed in invalid design patent).

[150] 376 U.S. at 232 ("To allow a State by use of its law of unfair competition to prevent the copying of an article which represents too slight an advance to be patented would be to permit the State to block off from the public something which federal law has said belongs to the public."); *see also Compco*, 376 U.S. at 238 ("[W]hile the federal patent laws prevent a State from

Therefore, Supreme Court precedent creates a clear rule that patent law preempts state laws that provide exclusive rights over information that is the subject of federal patent law. If a publicly disclosed invention does not meet the criteria for patentability or is not covered by a valid patent, the Court has interpreted federal patent law to provide the public with an affirmative right to freely use the public information.[151] States cannot directly interfere with that affirmative right. Yet when state laws merely impact the patent policy goals, such as by making patent protection more or less valuable, the Court has found that state law is not preempted.

The primary example of a state law that does not directly interfere with the use of information in the public domain but may nevertheless impact patent policy goals is trade secret protection. Trade secret law generally allows a trade secret holder to stop others from copying confidential, commercially valuable information or otherwise acquiring such information through improper means.[152] A trade secret may last indefinitely, so long as the information is not publicly disclosed.[153] Trade secret protection may attach to confidential information covering potentially patentable inventions or to information that is not patent eligible subject matter, such as customer lists or market analyses.[154]

By providing an alternative means to gain exclusive rights over potentially patentable inventions, trade secret law may undermine incentives for inventors to seek patent protection. With trade secret protection, inventors may choose to keep their inventions confidential, rather than publicly disclose information about their inventions. In turn, the lack of disclosure might impede the ability of others to make

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prohibiting the copying and selling of unpatented articles, they do not stand in the way of state law, statutory or decisional, which requires those who make and sell copies to take precautions to identify their products as their own.").

[151] The Court also pointed to the important public interest in permitting competition in the use of ideas in the public domain when it overruled the doctrine of licensee estoppel, which, based in state contract law principles, prohibited patent licensees from challenging patent validity. *Lear, Inc. v. Adkins*, 395 U.S. 653, 668-70 (1969).

[152] *Kewanee Oil*, 416 U.S. at 474-76.

[153] *See* Camilla Hrdy & Mark Lemley, *Abandoning Trade Secrets*, 73 STAN. L. REV. 1, 4 (2021) (describing conventional wisdom and arguing that trade secrets can be abandoned).

[154] *Kewanee Oil*, 416 U.S. at 477 ("Novelty, in the patent law sense, is not required for a trade secret.").

further innovations based upon public information. This is particularly true since trade secrets, unlike patents, can last indefinitely. Nonetheless, the Supreme Court held in *Kewanee Oil Co. v. Bicron Corp.*, that patent law does not impliedly preempt state trade secret protection.[155]

To determine whether state trade secret laws posed an impermissible obstacle to the goals of patent law, the Court considered the magnitude of the impact trade secret protection would likely have on patent policy goals. Even though trade secret laws could provide exclusive rights over potentially patentable inventions that are kept confidential, the Court doubted that this would have a significant impact on the patent policy goal of encouraging public disclosure of patentable inventions. Given differences between trade secrets and patents, the Court concluded that trade secret law was unlikely to deter individuals from publicly disclosing their inventions and seeking patent protection.[156] Trade secret law protects against disclosure or unauthorized use of trade secrets, but it does not protect against independent creation or reverse engineering by third parties.[157] Patents, meanwhile, provide patent holders remedies even when someone reverse engineers or independently creates the patented invention.[158] Because patent protection is stronger in this sense—and because trade secret misappropriation can be difficult to prove—the Court concluded that the risk that an inventor would choose to rely on trade secret protection for a patentable invention was "remote."[159]

With respect to patent law's primary goal of encouraging innovation, the Court similarly found the impact too little to pose an

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[155] 416 U.S. 470, 493 (1974).

[156] *Kewanee Oil*, 416 U.S. at 489-90. In a concurring opinion, Justice Marshall disagreed about whether trade secret law might deter disclosure of patentable inventions, noting that trade secrets can last for "unlimited duration." *Id.* at 493-94. Nonetheless, he found no conflict with patent law, which he viewed as encouraging disclosure rather than seeking to affirmatively require disclosure of patentable inventions. *Id.* at 494.

[157] *Id.* at 475-76.

[158] *Id.* at 477-78.

[159] *Kewanee Oil*, 416 U.S. at 489-90. With respect to inventions where the inventor was unsure whether the invention would meet the standards of patentability, the Court reasoned that in most cases the inventor would seek patent protection anyway due to the "potential rewards of patent protection." *Id.* at 488. Moreover, it noted that discouraging inventors from obtaining invalid patents would help promote the federal policy of allowing free use of information in the public domain. *Id.* at 488-89.

obstacle to federal patent policy. It noted that trade secret protection aims to encourage innovation as well, so its goals are similar to that of patent law.[160] Although there may be some concern that keeping information confidential will interfere with overall progress by impeding follow-on innovation, the Court reasoned that this concern was unlikely. In the Court's view, trade secret protection was unlikely to impede technological progress because others would likely independently discover most patentable inventions anyway, notwithstanding the decision by one individual to keep their invention as a trade secret.[161]

Finally, trade secret protection did not interfere with the third policy goal of patent law: protecting free access to information in the public domain. Unlike the state laws in cases such as *Bonito Boats*, which gave exclusive rights over publicly available information,[162] trade secret protection only applies to confidential information that is not in the public domain.[163]

Therefore, because state trade secret protection did not place a significant burden on the federal goals of encouraging disclosure, promoting innovation, and providing free access to information in the public domain, the Court held that patent law does not preempt state trade secret protection.[164] State trade secret protection remains commonplace today.[165]

2. Contracts Involving Patent Eligible Inventions

Beyond allowing for trade secret protection, state law can also enforce royalty agreements related to trade secrets, even when the trade secret involves a potentially patentable invention. In *Aronson v. Quick Point Pencil Co.*, the Supreme Court held that federal patent law did not preempt state contract law from enforcing royalty payments for

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[160] *Id.* at 484.

[161] *Id.* at 490-91.

[162] *See supra* notes 143-44 and accompanying text.

[163] *Kewanee Oil*, 416 U.S. at 480-81.

[164] *Id.* at 493. The Court also noted that Congress had never expressly preempted state trade secret law despite a long historical tradition of state trade secret protection, further supporting that Congress did not intend for patent law to preempt state trade secret protection. *Id.*

[165] Christopher Zirpoli, An Introduction to Trade Secrets Laws in the United States, Cong. Res. Serv. (2023).

a potentially patentable invention when the parties entered into the agreement before the invention was publicly disclosed.[166]

In *Aronson*, a patent applicant entered into a contract while her patent application for a keyholder was pending, but before the keyholder was publicly disclosed.[167] The parties agreed that the licensee would pay a royalty of 5% of sales to the patent applicant in exchange for the exclusive right to make and sell the keyholders described in the patent application.[168] If the patent did not issue within five years, however, the parties also agreed that royalty payments would be reduced to 2.5% of sales.[169] A patent ultimately did not issue.[170] After paying royalties for fourteen years, the licensee sued, arguing that patent law preempted state contract law that would make the agreement enforceable.[171]

In rejecting the preemption challenge, the Court noted that federal law does not displace the traditional authority of states to regulate commercial agreements simply because an agreement relates to intellectual property that "may or may not be patentable."[172] Similar to its analysis in *Kewanee*, the Court then considered the magnitude of the likely impact that this sort of agreement might have on patent policy goals. Although the Court acknowledged it would have some impact, it concluded that enforcement of the royalty agreement was not significant enough to present an obstacle to accomplishing the goals of federal patent law.[173] The Court concluded that concerns that allowing these sorts of contracts would discourage people from seeking patents were speculative, since the patent applicant could have made more money had she obtained a patent.[174]

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[166] 440 U.S. 257 (1979). Patent holders cannot collect royalties on a patent license, however, after the patent expires. Kimble v. Marvel Entertainment, 576 U.S. 446 (2015).

[167] *Aronson*, 440 U.S. at 259.

[168] *Id.* at 259.

[169] *Id*. at 259.

[170] *Id*. at 260.

[171] *Id*. at 260.

[172] *Id*. at 262.

[173] *Aronson*, 440 U.S. at 262-63 (describing the primary goals as encouraging innovation, promoting disclosure, and allowing free use of ideas in the public domain).

[174] *Id.* 263-64. Moreover, although the agreement ultimately required royalties for using information in the public domain, the Court explained that it did not conflict with the goal of promoting disclosure because the invention

### 3. Pharmaceutical Patent Exceptionalism

The above analysis shows that the Supreme Court has been reluctant to hold that state regulation is preempted by patent law based on facial challenges that speculate about how a state law may impact patent policy goals. Some level of impact on patent policy goals is not enough to preempt state regulation.[175] The only situations where the Court has found state laws to be preempted by patent law are in contexts where Congress has made an affirmative judgment that the information should be in the public domain—because it either does not meet the federal standards for patentability or because a patent covering the information has expired.[176] Yet outside this context, the Court has construed the preemptive scope of patent law narrowly. In *BIO v. DC*, the Federal Circuit departed from this general approach to the preemption analysis by broadly interpreting patent law to preempt the D.C. law based on speculation about how the D.C. law might impact patent policy goals.[177]

In *BIO v. DC*, the court concluded that the D.C. law posed an impermissible obstacle to patent policy simply because it sought to impact the financial rewards of patent holders.[178] The mere fact that a state regulation impacts financial rewards, and therefore innovation incentives, however, is not sufficient to find preemption under the Supreme Court's approach. In the Supreme Court cases discussed above, some level of impact on patent policy goals was not enough to

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had not been publicly disclosed at the time of the agreement, and the agreement ultimately led to the keyholder design coming into the public domain. *Id.* at 263.

[175] *See supra* Part II.B.1-B.2.

[176] *See supra* notes 136-51 and accompanying text.

[177] *BIO v. DC*, 496 F.3d 1362, 1374 (Fed. Cir. 2007) (reasoning that the D.C. law "stands as an obstacle to the federal patent law's balance of objectives" because it "is a clear attempt to restrain [] excessive prices, in effect diminishing the rewards to patentees in order to provide greater benefit to District drug consumers").

[178] *BIO v. DC*, 496 F.3d at 1374 ("The Act is a clear attempt to restrain those excessive prices, in effect diminishing the reward to patentees in order to provide greater benefit to District drug consumers."). It is worth noting that the Supreme Court cases discussed above do not articulate increasing financial rewards as a goal of patent law. The court relied exclusively on Federal Circuit precedent in its discussion of this goal of patent law. *Id.* at 1372-73. Financial rewards are relevant to the goals of patent law to the extent that they impact incentives to innovate. *See id.*

preempt state law, particularly in the context of facial challenges based on speculation.

In *Kewanee*, for example, the Court acknowledged that state trade secret protection would affect incentives to publicly disclose information and might impede follow-on innovation.[179] But it concluded that those impacts were not enough to pose an obstacle to federal patent policy given the remaining strong incentives to seek patent protection and the likelihood of continuing technological progress through independent invention.[180] Similarly, the royalty agreement at issue in *Aronson* had some impact on access to public information and could influence incentives to obtain patents, but the Court again concluded that the impact was not enough to create an obstacle to federal patent policy.[181] The existence of trade secret protection and royalty agreements impacted the value of patents by providing an alternative means for holding exclusive rights over potentially patentable inventions, but this was not enough for patent law to preempt state law.[182]

In contrast with the Supreme Court's approach, the Federal Circuit did not analyze whether the D.C. law's impact on innovation incentives imposed a significant enough burden to create an obstacle to patent policy goals. Simply because the D.C. law would "diminish[] the reward to patentees," the court concluded that it was "contrary to the goals established by Congress in the patent laws."[183] The court did not analyze the extent to which the law would reduce financial rewards, or more significantly, whether that impact would be enough to impact patent law's overarching goal of encouraging innovation.[184]

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[179] *Kewanee Oil*, 416 U.S. at 487-90.

[180] *Kewanee Oil*, 416 U.S. at 489-92.

[181] *Aronson*, 440 U.S. at 262-63.

[182] Moreover, even when the Court considered a regulation that directly impacted patent rights in *Allen v. Riley*, it considered the magnitude of the burden on patent rights. Because the state law imposing additional procedural requirements on patent transfers did not place an unreasonable burden on the exercise of the federally granted right to transfer patents, patent law did not preempt the state regulation of commercial transactions. *See supra* Part II.A.2.

[183] *BIO v. DC*, 496 F.3d at 1374.

[184] The court also did not consider the D.C. law's impact on the other goals of federal patent law that the Supreme Court has articulated, including public disclosure of information and promoting follow-on innovation through public access to information in the public domain. *See supra* Part II.B.1.

The opinion therefore creates another special rule for pharmaceutical patents: any impact on financial rewards for pharmaceutical patent holders can be enough to preempt state law. It seems to assume that any decrease in profits earned on patented drugs for pharmaceutical companies will significantly decrease innovation. Yet this assumption is not necessarily true. Just as trade secret protection might not interfere with technological progress to a significant degree, drug price regulation also might not interfere with technological progress to a significant degree.

By targeting excessive prices, the D.C. law would not necessarily impose a significant burden on the incentives to develop new drugs. Many critiques of high drug prices rest on the notion that prices are higher than needed to encourage research and development of new, socially beneficial drugs.[185] If prices are higher than needed to provide profits on the risky investments in pharmaceutical research and development, then prices could go down without significantly impacting the incentives of companies to continue developing new drugs. Given evidence that drug companies at least sometimes earn more than needed to provide reasonable profits on their investments in drug development, price regulation could theoretically reduce financial rewards without significantly reducing incentives to develop new drugs.[186] Estimates of the likely impact of the Medicare Drug Price Negotiation Program, for example, suggest that the ultimate impact on drug development will be quite modest, even though the program will reduce the prices that Medicare and its beneficiaries pay for some prescription drugs.[187]

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[185] *See, e.g.*, CHARLES SILVER & DAVID HYMAN, OVERCHARGED: WHY AMERICANS PAY TOO MUCH FOR HEALTH CARE 56 (2018) ("Even factoring in the cost of Gilead's unsuccessful research, Sovaldi is priced far higher than Gilead's research and development (R&D) costs could ever justify."); Hannah Brennan, Amy Kapczynski, Christine Monahan, & Zain Rizvi, *A Prescription for Excessive Drug Pricing: Leveraging Government Patent Use for Health*, 18 YALE J. L. & TECH. 275, 319 (2016) (arguing for compulsory patent licenses when there is a "likelihood that firms command rents in excess of risk-adjusted R&D costs plus a reasonable profit"); Nancy Yu et al., *R&D Costs for Pharmaceutical Companies Do Not Explain Elevated US Drug Prices*, HEALTH AFFAIRS (Mar. 7, 2017).

[186] *See supra* note 185 and accompanying text.

[187] Matthew Vogel et al, *Medicare Price Negotiation and Pharmaceutical Innovation Following the Inflation Reduction Act*, Nat. Biotech. (2024) ("Our results suggest that the IRA's reduction in overall industry revenue will be

Furthermore, because the D.C. law preserved market exclusivity for patented drugs, it did not necessarily interfere with patent law's goal of providing an innovation incentive through the right to exclude. By allowing patent holders to exclude competitors from the market (or collect royalties from them), patent law generally allows patent holders to obtain greater profits than they would with direct competition. The D.C. drug price law did not interfere with that system. Even if a state imposes price regulations on patented drugs, drug manufacturers may still make more money than they would if they were competing directly with generics.[188] As discussed above, some scholars have predicted that pharmaceutical companies may prefer Medicare price negotiation to direct generic competition, at least in some contexts.[189] So long as the state law allows drug companies to continue earning profits on new drugs, then exclusivity remains a tool to encourage drug development.

Therefore, it is possible that a law can affect the financial rewards that a drug company earns on a patented drug without interfering with the primary goal of federal patent law: encouraging innovation. Yet the Federal Circuit did not even consider the magnitude of the D.C. law's likely impact on financial rewards for drug companies or its likely impact on innovation incentives. That special rule for state regulations impacting pharmaceutical patents is not warranted.[190]

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modest, will not affect most top-selling drugs and will not likely result in large-scale defunding of research and development."); Letter from Cong. Budget Office to Rep. Arrington (Dec. 21, 2023) ("CBO estimated that over the next 30 years, 13 fewer new drugs (of 1,300 estimated new drugs) will come to market as a result of the new law.").

[188] *See* Rai, Sachs, & Price, *supra* note 119, at 72-75 (arguing that small molecule drug manufacturers may likely prefer Medicare price negotiation to direct competition with a generic based on a comparison of likely price decreases due to price negotiation and generic competition).

[189] *See supra* Rai, Sachs, & Price, *supra* note 119, at 72-82.

[190] Moreover, just as the D.C. law's impact on technological progress was speculative, so was its impact on the other goals of patent law articulated by the Supreme Court: encouraging public disclosure and promoting follow-on innovation by providing public access to information in the public domain. As long as state laws preserve the ability for drug companies to profitably produce new drugs, drug companies will still be encouraged to obtain patents and publicly disclose information about their inventions, which then will become part of the public domain when the patents expire.

## III. EXCEPTIONALISM WITHIN THE PHARMACEUTICAL INDUSTRY

Given that the *BIO v. DC* opinion relied on the Hatch-Waxman Act, which contains provisions that govern both FDA law and patent law, it is worth considering whether federal legislation governing the pharmaceutical industry beyond patent law supports the broad approach to preemption taken by the Federal Circuit for pharmaceutical patents. Unlike some industries that patent holders may enter, the pharmaceutical industry is subject to extensive federal regulation, including through FDA regulation and federal regulation of health insurance. This Part explores Supreme Court precedent involving preemption challenges to state regulation of these aspects of the pharmaceutical industry.

Based on an analysis of these cases, this Part contends that the *BIO v. DC* opinion takes an exceptionally broad approach to federal preemption compared to the Supreme Court's approach to preemption in the pharmaceutical industry generally. In contexts involving state regulation related to prescription drug safety and insurance coverage, the Court has continued its traditional approach of construing statutes narrowly to avoid preemption, acknowledging that Congress left space for states to regulate in ways that may affect the profits earned by drug companies and rejecting facial challenges based on speculation about how state laws might impact federal policy goals. The Federal Circuit, in contrast, interpreted patent law to broadly preempt state regulation based on inferences from legislative history and speculation about impacts on federal policy goals.

### *A. The Preemptive Scope of FDA Law*

The Federal Circuit's reliance on the Hatch-Waxman Act in the *BIO v. DC* opinion may suggest that the court concluded that Congress struck a balance between innovation incentives and access to medicine in that Act that preempts state regulation that impacts that balance.[191] Several Supreme Court cases decided in the years since *BIO v. DC* specifically considered whether FDA law and the Hatch-Waxman Act

[191] *See* BIO v. DC, 496 F.3d 1362, 1373-74 (Fed. Cir. 2007) ("The underlying determination about the proper balance between innovators' profit and consumer access to medication, though, is exclusively one for Congress to make."); *see also* BIO v. DC, 505 F.3d 1343, 1346-47 (Fed. Cir. 2007) (Gajarsa, J., concurring in the denial of rehearing en banc) (emphasizing the significance of the Hatch-Waxman Act).

preempted state regulation in another context: state tort law regarding drug labeling requirements. This Section analyzes those cases to consider whether they support a conclusion that the Hatch-Waxman Act broadly preempted state regulation impacting the balance between innovation incentives and access to medicine. It argues that the Supreme Court cases do not support such an inference, reflecting a different approach to statutory interpretation than the Federal Circuit.

1. Supreme Court Precedent

State tort law has long provided remedies for individuals injured by drug products, based on claims such as a failure to warn about risks. The Supreme Court has considered several preemption cases related to failure to warn claims for prescription drugs, based on FDA regulation of drug labels. Although the FDA extensively regulates warnings on prescription drug labels, the Supreme Court has still allowed state tort claims to assert that additional warnings on labels are required. State tort law is generally not preempted so long as it would be possible to comply with FDA regulations while providing the additional warning.

In *Wyeth v. Levine*, the Supreme Court held that a state failure to warn claim against a brand drug manufacturer was not preempted by FDA law.[192] In that case, a patient developed gangrene after receiving an injection of a brand name drug.[193] A jury awarded damages based on a finding that the manufacturer did not provide adequate warnings and instructions in the drug label about risks associated with a certain method of injecting the drug.[194] The drug manufacturer argued that state tort claims such as this one, which rely on the theory that different labeling was needed to make a drug reasonably safe, were preempted by the FDA's judgments about drug labels.[195] The Supreme Court, however, held that state tort claims against brand drug manufacturers are not preempted under these circumstances.[196]

In concluding that there was no federal preemption, the Court applied the presumption against preemption and emphasized the lack of an express preemption clause.[197] Given that Congress included an

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[192] 129 S. Ct. 1187, 1204 (2009).

[193] *Wyeth*, 129 S. Ct. at 1191.

[194] *Id*. at 1193-94.

[195] *Wyeth*, 129 S. Ct. at 1193.

[196] *Id*. at 1204 (rejecting theories based on both impossibility and obstacle preemption).

[197] *Id*. at 1194-96.

express preemption clause in laws regulating medical devices but not prescription drugs, the Court inferred that Congress's silence on the issue of preemption meant that Congress did not intend to preempt state tort litigation regarding prescription drug safety.[198] Moreover, the Court noted that Congress had taken care to preserve state law generally. In the 1962 amendments to the Food, Drug, and Cosmetic Act, Congress included a savings clause, which stated that state law would only be invalidated upon a "direct and positive conflict" with the FDCA.[199]

Furthermore, the Court concluded that the state tort claim did not pose an impermissible obstacle to the goals of FDA regulation. It noted that both FDA law and state tort law aimed to promote consumer protection.[200] Looking to practical impacts of the law, the Court observed that state law might help achieve federal consumer protection goals, given that the FDA had limited resources to monitor all drugs on the market and that manufacturers typically had better information about the safety of their drugs, particularly when evidence of new risks emerges after FDA approval.[201] Furthermore, in this case, the state tort suit did not interfere with any balancing judgment made by the agency—the FDA had not considered and rejected the argument that an additional warning should be included on the label.[202]

Therefore, the Court has interpreted federal FDA law to leave at least some room for state regulation of prescription drug safety. In other cases, however, it found that the Hatch-Waxman Act specifically preempts state tort claims brought against generic manufacturers, rather than brand manufacturers.[203] Notably, in these cases, preemption was based on impossibility preemption, not obstacle

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[198] *Id*. at 1200. The Court also noted that Congress expressly preserved state product liability claims when it preempted certain requirements regarding over-the-counter drugs and cosmetic products. *Id.* at 1200 n.8. With respect to the long tradition of state tort litigation, the Court cited *Bonito Boats*, which noted the long history of state trade secret law. *Id.* at 1200. Although the FDA took the position that state law was preempted, the Court declined to defer to FDA's view. *Id.* at 1200-02.

[199] *Id*. at 1196.

[200] *Id.* at 1199.

[201] It also noted that state tort suits serve a distinct compensatory function. *Id*. at 1202.

[202] *Wyeth*, 129 S. Ct. at 1203-04 & n.14 ("[T]he FDA did not consider and reject a stronger warning against IV-push injection of Phenergan.").

[203] Mut. Pharm. Co. v. Bartlett, 133 S. Ct. 2466, 2480 (2013); PLVIA, Inc. v. Mensing, 131 S. Ct. 2567, 2582 (2011).

preemption.[204] Because the Hatch-Waxman Act requires generic drug labels to be equivalent to brand labels, generic manufacturers cannot unilaterally add warnings to drug labels.[205] Instead, additional warnings must be initiated by the brand manufacturer or the FDA.

### 2. Pharmaceutical Patent Exceptionalism

These Supreme Court cases involving FDA preemption raise several tensions with *BIO v. DC*, both substantively and in terms of the approach to statutory interpretation. First, as a substantive matter, *Wyeth* casts doubt on the Federal Circuit's conclusion that Congress exclusively reserved judgment about the balance between innovation incentives and access to medicine to the federal government. Legal scholars have recognized regulations beyond patents influence both innovation incentives and access to medicine.[206] Decisions about the FDA approval process, for example, influence how expensive the drug development process is, which in turn, can influence investment decisions in pharmaceutical research and development.[207] State tort claims can also influence this balance. Broader availability of state tort claims against brand drug manufacturers could increase costs of drug development, which in turn, could increase drug prices (restricting access to medicine) or decrease profits earned by drug companies

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[204] *Bartlett*, 133 S. Ct. at 2476-78; *Mensing*, 131 S. Ct. at 2577-79. In a dissenting opinion, Justice Breyer concluded that a state tort claim would not be preempted under either a theory of impossibility preemption or obstacle preemption. *Bartlett*, 133 S. Ct. at 2482 (Breyer, J., dissenting) ("I have found no convincing reason to believe that removing this particular drug from New Hampshire's market or requiring damage payments would be so harmful that it would seriously undercut the purposes of the federal statutory scheme.").

[205] *Bartlett*, 133 S. Ct. at 2476-78; *Mensing*, 131 S. Ct. at 2577-79 ("If the Manufacturers had independently changed their labels to satisfy their state-law duty, they would have violated federal law.").

[206] *See* Daniel J. Hemel & Lisa Larrimore Ouellette, *Beyond the Patents-Prizes Debate*, 92 TEX. L. REV. 303, 315-26 (2013); Daniel J. Hemel & Lisa Larrimore Ouellette, *Innovation Policy Pluralism*, 128 YALE L.J. 544, 593-601 (describing different innovation incentives for drugs).

[207] *See* Rachel E. Sachs, Nicholson Price, & Patricia J. Zettler, *Rethinking Innovation at FDA*, 104 B.U. L. REV. 513, 531 (2024); Rebecca Eisenberg, *The Role of the FDA in Innovation Policy*, 13 MICH. TELECOMM. & TECH. L. REV. 345, 359-84 (2007).

(decreasing innovation incentives).[208] Nonetheless, the Supreme Court interpreted FDA law to permit state tort claims.

Second, the Supreme Court cases cast doubt on the Federal Circuit's characterization of federal policy goals. The *BIO v. DC* opinion relied heavily on legislative history statements about the goal of promoting incentives to innovate through patent term extension in the Hatch-Waxman Act.[209] The Supreme Court drug labeling decisions, on the other hand, focus on a different aspect of the goals of the Hatch-Waxman Act: encouraging generic competition. In its decisions finding that state tort claims against generic manufacturers were preempted, the Court explicitly acknowledged that this created a system where tort claims could usually only be brought based patented drugs. Many state laws encourage or require prescribing generic drugs once a generic enters the market.[210] Therefore, since the Court concluded that state tort claims were preempted against generic manufacturers but not against brand manufacturers, the practical result would be that state tort claims are typically only available during the period when a drug remains covered by a patent. Nonetheless, the Court concluded that this was the system Congress created, observing that the Hatch Waxman-Act sought to encourage generic competition in the pharmaceutical industry.[211]

The focus on encouraging generic competition—which lowers drug prices and expands access to medicine—shows how state drug price regulation may not necessarily be in tension with federal policy goals. Drug price regulation can serve a complementary role to the goal of expanding access to medicine by monitoring excessive prices charged before generics enter the market. And as discussed above, price

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[208] *See Wyeth*, 129 S. Ct. at 1204 (Breyer, J., concurring) ("I also note that some have argued that state tort law can sometimes raise prices to the point where those who are sick are unable to obtain the drugs they need.").

[209] *See id.* at 1373.

[210] *Mensing*, 131 S. Ct. at 2581-82 & n.9 (observing that new information about risks infrequently arises when generics are prescribed because drugs have often been already used during the period of patent protection for years).

[211] *Mensing*, 131 S. Ct. at 2582 ("Indeed, it is the special, and different, regulation of generic drugs that allowed the generic drug market to expand, bringing more drugs more quickly and cheaply to the public."); *id.* at 2574 (describing the Hatch Waxman Act requirements that "allow[] generic manufacturers to develop generic drugs inexpensively"); *Bartlett*, 133 S. Ct. at 2471 ("In order to provide a swifter route for approval of generic drugs, Congress passed the Drug Price Competition and Restoration Act of 1984, popularly known as the "Hatch-Waxman Act") (citations omitted).

regulation may not significantly impact innovation incentives.[212] It may even encourage drug companies to direct investments to more socially valuable medicine.[213]

Third, the Supreme Court cases represent a different approach to statutory interpretation, showing a greater reluctance to infer intent to preempt through congressional silence and federal inaction. In *Wyeth*, for example, the Court considered the lack of an express preemption provision in context with other provisions of FDA law. The Court emphasized that Congress did not expressly preempt state tort claims related to prescription drugs, even though it expressly preempted claims in other areas, such as medical device regulation.[214] Moreover, it pointed out that Congress had included a savings clause in the FDCA that limited preemption to state law that created a "direct and positive conflict" with the Act.[215] Furthermore, it applied the presumption against preemption to narrowly construe the preemptive scope of the Hatch-Waxman Act.[216]

The Federal Circuit, in contrast, did not consider the presence of express preemption clauses in other statutes nor did it apply the presumption against preemption.[217] The failure to consider other preemption provisions is especially notable because these provisions suggest that Congress could have expressly preempted state regulations related to prescription drugs if it wanted to.[218] Moreover,

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[212] *See supra* Part II.B.3.

[213] *See* Daniel Hemel & Lisa Ouellette, *Valuing Medical Innovation*, 75 STAN. L. REV. 517, 545-49 (2023).

[214] Congress also preempted certain state requirements concerning over-the-counter drugs and cosmetics but expressly preserved state product liability claims. *Wyeth*, 129 S. Ct. at 1200 & n.8.

[215] *Id*. at 1196.

[216] *Id.* at 1194-96.

[217] *See* BIO v. DC, 505 F.3d 1343, 1351 (Fed. Cir. 2007) (Dyk, J., dissenting from the denial of rehearing en banc). In his concurrence from the denial of rehearing en banc, Judge Gajarsa seems to suggest that the presumption against preemption was overcome by evidence of the "clear and manifest purpose" of Congress, but that conclusion is in tension with the Supreme Court's analysis about clear evidence of congressional intent to preempt state law in *Wyeth*. *See id.* at 1345 (Gajarsa, J., concurring in the denial of rehearing en banc).

[218] *See id*. at 1200 ("Its silence on the issue, coupled with its certain awareness of the prevalence of state tort litigation, is powerful evidence that Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness.").

the savings clause in the FDCA suggests that Congress might have been operating against the background assumption when creating a new law relating to FDA regulation that state law would only be preempted if it directly conflicted with a federal regulation.[219]

Nothing in patent law warrants the Federal Circuit's divergent approach to statutory interpretation. Congress could just as easily include an express preemption clause in patent statutes as it could in FDA statutes. Congress likely would have been aware of state police powers when drafting patent laws, just as it was likely aware of state tort law when drafting FDA laws. The Supreme Court considered the presence of express preemption clauses in some contexts, but not others, as relevant to the statutory interpretation analysis. Yet the Federal Circuit did not consider express preemption clauses in other areas related to FDA regulation.

Furthermore, beyond considering other statutory provisions and the presumption against preemption, the Supreme Court also considered whether there had been any relevant federal action with respect to the drug labeling claim. In *Wyeth*, the Court noted in rejecting the obstacle preemption challenge that the state tort suit did not seek to overturn any specific balancing judgment made by the FDA.[220] There, the FDA had not considered whether the additional warning required by state tort law should have been added to the drug's label.[221] Similarly, in *BIO v. DC*, the federal government had not made any specific balancing judgments about whether the drug prices deemed excessive under the D.C. law were excessive or not. No provision in the patent laws or the Hatch-Waxman Act regulates drug prices, nor does either law authorize any agency to do so. Yet the Federal Circuit did not consider this at all, highlighting another inconsistency in its approach to statutory interpretation.[222]

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[219] Indeed, the Supreme Court cases finding state laws preempted under the Hatch-Waxman Act involved this sort of situation: it would have been impossible for a generic drug manufacturer to simultaneously comply with state tort duties and the requirements of the Hatch-Waxman Act. *See supra* notes 203-05 and accompanying text.

[220] *Wyeth*, 129 S. Ct. at 1203-04 & n.14 ("[T]he FDA did not consider and reject a stronger warning against IV-push injection of Phenergan.").

[221] *Id.*

[222] Instead, it assumed that any reduction in profits would interfere with patent policy goals. *See* BIO v. DC, 496 F.3d 1362, 1374 (Fed. Cir. 2007).

### *B. The Preemptive Scope of Health Insurance Laws*

Outside of FDA regulation, the federal government also regulates the pharmaceutical industry through insurance laws. Given the role that insurance coverage plays in helping individuals afford prescription drugs, states have enacted some drug pricing reforms that focus on insurance coverage. In response to these state drug pricing reform efforts, the Supreme Court has considered preemption challenges based on federal insurance laws as well, including Medicaid law and the Employee Retirement Income Security Act of 1974 ("ERISA").

Supreme Court preemption cases involving health insurance laws follow a similar analysis that the Court has followed in preemption cases in both patent law and FDA law. The cases reflect a tendency to avoid invalidating state laws based on hypothetical assertions about how the laws may impact federal policy goals. Similar to the FDA context, these cases allow States room to regulate aspects of the prescription drug market, notwithstanding extensive federal regulation. Once again, the Federal Circuit's reasoning in *BIO v. DC* is inconsistent with the Supreme Court's approach.

#### 1. Supreme Court Precedent

Supreme Court preemption cases involving health insurance regulations have followed a similar analysis to the Court's obstacle preemption analysis in *Kewanee*: the Court has considered whether the state regulation posed a significant obstacle to the goals of federal laws, not whether the state law merely impacted federal goals at all.[223] And similar to the result in *Kewanee*, it concluded that federal law does not preempt state regulation just because the state law has some impact on federal goals.[224]

One Supreme Court case in the insurance context dealt with a preemption challenge based on Medicaid law. Congress created the Medicaid program in 1965 to provide financial assistance to States that help reimburse health care costs for low-income individuals.[225] In 1990, Congress created a prescription drug rebate program for Medicaid.[226] The Medicaid rebate program requires drug companies to provide

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[223] *See supra* Part II.B.1.

[224] *See supra* Part II.B.1.

[225] PhRMA v. Walsh, 123 S. Ct. 1855, 1861 (2003).

[226] *Walsh*, 123 S. Ct. at 1861-62.

rebates to Medicaid programs as a condition of participating in Medicaid.[227] If a manufacturer agrees to provide rebates to Medicaid, state Medicaid plans must cover most FDA-approved drugs. States can place conditions on coverage though, such as a requirement of prior approval before a drug is dispensed (known as "prior authorization" requirements).[228]

In 2000, the Maine legislature passed a law that sought to reduce prescription drug prices for residents within the State.[229] The law created the Maine Rx program, which would allow individuals to purchase drugs from retail pharmacies at discounted prices, similar to the prices provided to Medicaid.[230] If a manufacturer did not agree to provide rebates for the Maine Rx program, the State would impose prior authorization requirements in the Medicaid program for drugs sold by the manufacturer.[231] Prior authorization requirements could in turn limit access to the drugs for Medicaid beneficiaries.

An association of drug manufacturers challenged the Maine law, arguing that it was preempted by federal Medicaid law.[232] The district court granted a preliminary injunction. It reasoned that the Maine program created an obstacle to the administration of the Medicaid program, stating that "no matter how modest an obstacle the new prior authorization amounts to…it is an obstacle."[233] The Court of Appeals disagreed, concluding that the preemption challenge could not succeed

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[227] *Id*. at 1862. Discounts are required for both brand drugs and generics. For brand drugs, the rebates generally must be either the difference between the average price and best price the manufacturer offers or 15.1% of the average price, whichever is greater.

[228] *Id*. at 1862 ("[T]he law requires the State to provide coverage for that drug under its plan unless the State complies with one of the exclusion or restriction provisions of the Medicaid Act."). Prior authorization programs had to provide a response within 24 hours and a 72-hour supply of drugs for emergency situations. *Id.* Congress reenacted this law with minor amendments in 1993. *Id.*

[229] *Id.* at 1862.

[230] *Walsh*, 123 S. Ct. at 1862.

[231] *Id.* at 1863. Maine would also publish information about non-participating manufacturers. *Id.* It represented that it would not subject drugs to prior authorization requirements if drugs fulfilled "unique therapeutic function[s]." *Id.*

[232] The association also argued that the law reduced drug manufacturers market share. *Id*. at 1864. The association also raised a challenge under the dormant Commerce Clause, which the Court rejected.

[233] *Id*. at 1865 (quoting the district court opinion).

without evidence that the Maine law would "inflict inevitable or even probable harm" on Medicaid patients.[234] The Supreme Court then affirmed the Court of Appeals.[235]

In a plurality opinion applying the presumption against preemption, Justice Stevens reasoned that the district court was incorrect to conclude that any impediment to the ability of Medicaid patients to access drugs, "no matter how modest," was enough to preempt state law.[236] He explained that based on the evidence before the Court, the Maine law would only have a "minimal impact on Medicaid recipients' access to prescription drugs."[237] The mere fact that the Maine Rx law might impose a "modest impediment to access to prescription drugs at government expense" was not sufficient for preemption.[238] At that time, Justice Stevens noted that the actual impact of the state law on Medicaid was speculative.[239] If all manufacturers agreed to participate in the Maine Rx program, for example, there would be no impact on access to drugs for Medicaid beneficiaries.[240]

In a concurring opinion, Justice Breyer agreed that creating a "modest" impediment to the goals of the Medicaid program was insufficient for preemption.[241] He reiterated that the state program must "seriously compromise important federal objectives" to be

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[234] *Id*. at 1865-66. The district court emphasized that the Maine law altered the federal program to serve a purpose unrelated to Medicaid, though the Court concluded in that the Maine law conceivably served at least three Medicaid-related purposes, including creating cost savings. *Id.* at 1867-68.

[235] Notably, the Court did not consider whether the Maine law would be preempted if the CMS Secretary did not approve the change to Maine's Medicaid program. Instead, it considered whether the Maine law was preempted by the mere existence of the Medicaid statute. *Id*. at 1866-67.

[236] *Id*. at 1868.

[237] *Walsh*, 123 S. Ct. at 1869.

[238] *Id*. at 1870.

[239] *Id*. at 1870.

[240] *Id*. at 1870 ("If the committee determines prior authorization is required, that requirement may result in the delivery of a less expensive drug than a physician first prescribed, but on the present record we cannot conclude that a significant number of patients' medical needs—indeed, any patient's medical needs—will be adversely affected.").

[241] *Id*. at 1871-72 (Breyer, J., concurring).

preempted, and a proper preemption determination required a "more careful balancing of Medicaid-related harms and benefits."[242]

Similarly, the Supreme Court rejected an ERISA preemption challenge based on state regulation of reimbursement rates for pharmacy benefit managers. ERISA, a law governing employer-provided benefit plans, contains an express preemption clause of state laws that "relate to any employee benefit plan" covered by ERISA.[243] This express preemption clause uses broad language to preempt state regulation. The Supreme Court, however, has interpreted this express preemption clause to have some significant limits. In doing so, its interpretation of that clause has resembled the obstacle preemption analysis. Specifically, the Court has interpreted the preemption clause to mean that a state law is preempted if it has an impermissible connection to an ERISA plan.[244] To determine whether an impermissible connection exists, it considers ERISA's objectives—similar to the consideration of whether a state law poses an obstacle to the objectives of federal law.[245] Therefore, even where Congress expressly preempted state health insurance regulation, the Court has construed the scope of that provision by considering the magnitude of the impact of state regulations on the goals of federal law.

In *Rutledge v. Pharm. Care Management Ass'n*, the Court held that ERISA did not preempt an Arkansas law that regulated the price at which pharmacy benefit managers could reimburse pharmacies for drugs.[246] Pharmacy benefit managers are intermediaries between health insurance plans and pharmacies. In a typical business model, the pharmacy benefit manager reimburses the pharmacy for costs above a patient's copayment when a patient purchases a prescription

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[242] *Id.* at 1872 (Breyer, J., concurring) (quoting Arkansas Elec. Cooperative Corp. v. Arkansas Pub. Serv. Comm'n, 461 U.S. 375, 389 (1983)). Justice Breyer also urged the court to give deference to the views of HHS about whether the state program posed an obstacle to federal goals. *Id.* at 1872-73. Justice Thomas wrote a concurring opinion as well, taking an even narrower view of preemption and expressing skepticism of obstacle preemption generally. *Id.* at 1875, 1878 (Thomas, J., concurring). Justice Scalia also wrote a concurring opinion taking the view that the preemption challenge could be addressed solely by seeking enforcement of any failure to comply with Medicaid requirements through HHS. *Id.* at 1874 (Scalia, J., concurring).

[243] 141 S. Ct. at 479 (quoting 29 U.S.C. § 1144(a)).

[244] *Rutledge*, 141 S. Ct. at 479.

[245] *See id.* at 480.

[246] 592 U.S. 80 (2020).

drug from a pharmacy. The health insurance plan then reimburses the pharmacy benefit manager.[247] The amounts that pharmacy benefit managers reimburse pharmacies are based on contracts, which set reimbursement rates that may differ from the prices the pharmacy paid to acquire drugs from wholesalers.[248] The reimbursement rate from the health insurance plan often exceeds the amount the pharmacy benefit manager pays the pharmacy, which allows pharmacy benefit managers to earn profits.[249]

In response to concerns that reimbursement rates to pharmacies were often too low to cover the pharmacies' costs, Arkansas passed a law that requires pharmacy benefit managers to reimburse pharmacies at a price that is equal to or higher than the price paid by the pharmacy to acquire the drug.[250] An association representing pharmacy benefit managers challenged the law, arguing that it was preempted because it regulated health insurance plans covered by ERISA.[251] In a unanimous decision, the Supreme Court rejected the preemption challenge.[252]

The Court reasoned that the primary objective of ERISA was to create a uniform body of employee benefits law.[253] In light of this goal, the Court had previously concluded that ERISA primarily aimed to preempt state laws that require providers to structure benefit plans in particular ways, such as by requiring specific benefits or setting binding rules to determine beneficiary status.[254] Although a state law that required ERISA plans to adopt a particular scheme of substantive coverage might be preempted, the Court emphasized that a state law was not necessarily preempted for merely affecting an ERISA plan.[255]

The Court concluded that state regulations that merely increase costs or alter incentives for ERISA plans were not preempted so long as

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[247] *Rutledge*, 141 S. Ct. at 478.

[248] *Id*.

[249] *Id*

[250] *Id*. at 478-79.

[251] *Id*. at 479.

[252] Justice Barrett did not participate in the case. Justice Thomas wrote a concurring opinion, expressing skepticism over the Supreme Court's ERISA precedent which resembled "purposes and objectives" preemption that he has generally expressed skepticism of as an atextual mode of statutory interpretation. *Id*. at 483 (Thomas, J., concurring).

[253] *Rutledge*, 141 S. Ct. at 480. This uniform structure protected benefits and reduced administrative costs of conflicting rules in different states. *Id*.

[254] *Id*. at 480.

[255] *Id*.

the state laws did not force plans to adopt any particular scheme of substantive coverage.[256] Because the Arkansas law was merely a form of cost regulation, it was not preempted.[257] The Court acknowledged that if pharmacy benefit managers passed on their increased costs to health plans, the law may require health plans to pay more for drugs in Arkansas than in other states. Yet mere interference with cost uniformity was not enough to create ERISA preemption. Moreover, the Court reasoned that the impact of the Arkansas law was not "so acute that it will effectively dictate plan choices."[258] Therefore, the Arkansas law did not have an impermissible connection to an ERISA plan.[259]

2. Pharmaceutical Patent Exceptionalism

The Supreme Court cases involving the preemptive scope of health insurance laws reinforce the exceptional breadth of the preemption analysis in *BIO v. DC*. The Federal Circuit's reasoning is inconsistent with Supreme Court preemption cases in the health insurance context, both in terms of the general approach to obstacle preemption and in terms of substantive conclusions.

The first inconsistency relates to the courts' approaches to analyzing obstacle preemption. As discussed above, the *Walsh* decision shows a similar approach to obstacle preemption that the Supreme Court has followed in patent cases such as *Kewanee*.[260] *Walsh* reinforces the notion that for a state law to be preempted, it must pose a significant obstacle to accomplishing federal objectives. Speculation that a state law might pose an obstacle or will have some impact on the goals of federal law are not enough to show preemption. Just as state trade secret law might have some impact on the incentive to disclose patentable inventions and on technological progress, the Maine law might have some impact on Medicare beneficiaries' access to

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[256] *Id*. at 480-81 (discussing precedent finding no preemption for state laws that impacted costs for health insurance plans).

[257] *Id*. at 481.

[258] *Id*.

[259] *Id*. The law also did not "refer" to an ERISA plan because it did not apply directly or exclusively to ERISA plans. It applied to all pharmacy benefit managers, whether or not they managed an ERISA plan. The Court explained that pharmacy benefit managers also contract with healthcare plans not covered by ERISA, including Medicaid, Medicare, military, and marketplace plans. *Id.*

[260] *See infra* Part I.B.

prescription drugs.[261] Nonetheless, the Supreme Court clearly instructed that a mere potential impact, and even a modest impact, was not enough to preempt state regulation. Furthermore, even in the context of ERISA—where Congress included an express preemption clause—the Supreme Court concluded that Congress did not intend to preempt state drug price regulation that merely impacted the costs of ERISA plans.[262] For the same reasons discussed in Part II, the *BIO v. DC* opinion does not follow this approach—it found the D.C. law preempted based on mere speculation about its impact on patent policy goals and assumed that any impact on financial rewards was sufficient for preemption.[263]

The second inconsistency relates to the Federal Circuit's substantive conclusion that Congress reserved judgments about how to balance innovation incentives and access to medicine to the federal government.[264] Both *Walsh* and *Rutledge* show that even in the context of health insurance, where the federal government has extensively regulated, the Supreme Court has interpreted federal law to allow some state regulation of insurance coverage of prescription drugs, including state regulation to address concerns about high drug prices. Just as FDA regulation can impact both innovation incentives and access to medicine, so can health insurance regulation. Legal scholars have observed that government subsidies for health insurance can increase the number of patients who are able to afford drugs, operating as an innovation subsidy by increasing the profits that companies can make when they sell drugs.[265]

Congress made decisions that impacted this balance when it passed Medicaid laws and ERISA. Yet the Supreme Court concluded that it also left room for states to regulate in ways that impact these incentives. Regulations of pharmacy benefit manager reimbursement rates could predictably raise costs for health insurance plans and therefore influence their negotiations with drug manufacturers,

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[261] *See supra* notes 156-63 and accompanying.

[262] *Rutledge*, 141 S. Ct. at 481-83. ERISA shows another example of how Congress can include express preemption provisions when it intends to preempt state law.

[263] *See supra* Part II.B.3.

[264] *See* BIO v. DC, 496 F.3d 1362, 1372 (Fed. Cir. 2007).

[265] *See* Mark A. Lemley, Lisa Larrimore Ouellette, & Rachel E. Sachs, *The Medicare Innovation Subsidy*, 95 N.Y.U. L. Rev. 75 (2020); *see also* Hemel & Ouellette, *supra* note 206, at 315-26; Hemel & Ouellette, *supra* note 206, at 593-601 (describing different innovation incentives for drugs).

potentially decreasing insurance coverage of drugs and in turn, decreasing drug companies' profits and innovation incentives.[266] And in *Walsh*, drug companies argued that more prior authorization requirements on Medicaid plans would reduce the market share and sales for their drugs, which in turn, could predictably influence profits and innovation incentives.[267] Yet the Court concluded that Congress left room for states to make these sorts of judgments.[268] These decisions therefore cast further doubt on the Federal Circuit's conclusion that Congress precluded states from making decisions that impact this policy balance.

One potential argument for treating patents differently than other forms of pharmaceutical regulation is that patents, unlike FDA approvals and health insurance subsidies, are expressly mentioned in the Constitution.[269] Although the Constitution itself can displace state laws, most federal preemption derives from federal statutes.[270] One example of the Constitution directly precluding state regulation is the dormant Commerce Clause doctrine, which holds that the Commerce Clause implicitly prevents state actions that place an undue burden on

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[266] *See* Lemley, Ouellette, & Sachs, *supra* note 265, at 107-15; *Rutledge*, 141 S. Ct. at 483 (noting that the Arkansas law was not preempted "even if plans decide to limit benefits or charge plan members higher rates as a result.").

[267] *See* Pharm. Research & Mfrs. of America v. Walsh, 123 S. Ct. 1855, 1864 (2003).

[268] Regulatory limits on health insurance coverage, both from the federal government and states, also cast doubt on the notion that Congress intended for drug companies to have the unimpeded ability to earn profits without any price regulation.

[269] U.S. Const., art. I, sec. 8, cl. 8 ("Congress shall have the power… 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.").

[270] *See* Kansas v. Garcia, 589 U.S. 191, 202 (2020) ("In all cases, the federal restrictions or rights that are said to conflict with state law must stem from either the Constitution itself or a valid statute enacted by Congress."); Adkins et al., *supra* note 40, at 1 ("Preemptive federal statutes shape the regulatory environment for most major industries, including drugs and medical devices, banking, air transportation, securities, automobile safety, and tobacco.").

interstate commerce.[271] Perhaps a parallel doctrine could be inferred based on the IP Clause.[272]

The Supreme Court cases involving patent preemption, however, instruct that this sort of preemption would not arise simply because a state regulation impacts patent rights or patent policy goals.[273] Instead, Supreme Court patent preemption cases suggest the analysis would be similar to obstacle preemption generally, considering whether the state law places a significant burden on federal patent rights and policy. In *Allen*, for example, the Court considered whether a state regulation of patent transactions placed an unreasonable burden on the exercise of patent rights.[274] Similarly, in *Kewanee*, the Court considered whether state trade secret law was likely to significantly interfere with patent policy goals.[275] Therefore, the IP Clause of the Constitution does not provide a basis for treating pharmaceutical patents differently from other pharmaceutical regulations for preemption purposes.

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[271] Jonathan Nash, *Null Preemption*, 85 NOTRE DAME L. REV. 1015, 1035 (2010).

[272] It is worth noting that The IP Clause merely authorizes Congress to grant patents, similar to how the Commerce Clause authorizes Congress to regulate interstate commerce. The IP Clause appears in the same section of the Constitution that authorizes Congress to regulate interstate commerce. U.S. Const., art. I, sec. 8, cl. 3.

[273] *See supra* Part II.

[274] *See* Allen v. Riley, 203 U.S. 347, 355-57 (1906); *see also* Hrdy, *supra* note 43, at 319.

[275] *See Kewanee Oil*, 416 U.S. at 489-91. Moreover, the analysis under the dormant Commerce Clause involves a fact-specific balancing test—even-handed state actions are not unconstitutional merely because they impact interstate commerce. National Pork Producers Council v. Ross, 598 U.S. 356 (2023) ("But 'extreme caution' is warranted before a court deploys this implied authority."). State laws that facially discriminate against interstate commerce can violate the dormant Commerce Clause. Under analogical reasoning, this may support the Federal Circuit's reasoning in *BIO v. DC*, which emphasized that the D.C. law targeted patented drugs specifically. Supreme Court precedent, however, suggests that targeting patent rights alone is not enough for preemption. The statute in *Allen v. Riley* dealt with patent transactions only, and the Court found that it was not preempted because it did not place an unreasonable burden on patent rights. 203 U.S. 347, 355-57 (1906).

## IV. EXCEPTIONAL INSULATION FROM PRICE REGULATION

In addition to its inconsistency with Supreme Court preemption precedent involving patent law and pharmaceutical regulations, the *BIO v. DC* decision is also inconsistent with Supreme Court precedent involving preemption of state price regulation. Price regulation has historically fallen with states' traditional police powers, which include broad powers to regulate economic matters.[276] The Court has recognized some federal preemption of state price regulation though. In some contexts, the Supreme Court has found that affirmative federal regulation preempts state price regulation.[277] When the federal government is not affirmatively regulating prices, however, the Court has been reluctant to find preemption of state price regulation, particularly through implied preemption. This Part analyzes Supreme Court precedent related to potential regulatory voids created by preemption of state price regulation without affirmative federal regulation. It then argues that the Federal Circuit's decision in *BIO v. DC* departs from the Supreme Court's traditional approach of construing statutes to avoid regulatory voids.

### *A. Supreme Court Precedent on Regulatory Voids*

When the federal government does not regulate in a particular way, preemption of state regulation can lead to a regulatory void, where there is no regulation. In the price regulation context, preemption without federal price regulation would mean that industries could operate without any price regulation. Federal preemption without federal regulation has historically been rare.[278] The Supreme Court, however, has instructed that the fact that an area would remain unregulated does not automatically dispose of the preemption question. The federal government may preempt state regulation without

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[276] *See* Nebbia v. New York, 291 U.S. 502 (1934) (holding that state price controls are constitutional so long as they are reasonable and serve a legitimate public purpose); *see also* Kumar, *supra* note 31, at 39 (describing forms of state price regulation upheld by the Supreme Court).

[277] *See, e.g.*, Mississippi Power & Light Co. v. Mississippi, 487 U.S. 354 (1988) ("FERC-mandated allocations of power are binding on States, and States must treat those allocations as fair and reasonable when determining rates.").

[278] Nash, *supra* note 271, at 1017 ("[N]ull preemption has been historically uncommon.").

regulating itself when it has made an "authoritative federal determination that the area is best left *un*regulated."[279] Yet similar to its preemption jurisprudence generally, the Court has narrowly construed statutes that lack express preemption clauses, showing a reluctance to conclude to that Congress can implicitly create regulatory voids. Moreover, even when statutes contain express preemption clauses, the Court has considered the extent of federal regulation when interpreting the scope of the preemption clause.

1. Reluctance to Imply a Regulatory Void

When a statute does not expressly preempt state price regulation, the Court has declined to find that Congress intended to implicitly create a regulatory void. For example, in *Puerto Rico Department of Consumer Affairs v. Isla Petroleum Corp.*, the Supreme Court concluded that Congress did not preempt oil price regulation by Puerto Rico through silence.[280] In 1973, Congress gave the President authority to regulate oil prices in response to national shortages.[281] The law granting authority to the President contained an express preemption clause prohibiting state regulations that conflicted with a presidential order issued under the law.[282] The President's authority was temporary, and ultimately expired in 1981.[283] Several years after the federal law expired, the Puerto Rico Department of Consumer Affairs issued regulations governing oil prices in Puerto Rico.[284] Several companies challenged the regulations as preempted by federal law, arguing that by allowing the federal price regulation provisions to expire, Congress had made a decision that oil prices should be determined by the free market rather than regulation.[285]

The Supreme Court rejected this argument.[286] The Court noted that the preemption claim was "untypical," given both the absence of an express preemption provision and the absence of any existing federal

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[279] Arkansas Elec. Cooperative Corp. v. Arkansas Public Serv. Comm'n, 461 U.S. 375, 383-84 (1983).

[280] 485 U.S. 495 (1988).

[281] *Puerto Rico*, 485 U.S. at 497.

[282] *Id*.

[283] *Id*. at 497-98.

[284] *Id*. at 498-99.

[285] *Id*. at 499-500.

[286] *Puerto Rico*, 485 U.S. at 499 ("[T]he test for federal pre-emption of the law of Puerto Rico at issue here is the same as the test under the Supremacy Clause, U.S. Const., Art. VI, cl. 2, for pre-emption of the law of a State.").

regulation of oil prices.[287] Although it acknowledged that Congress can preempt state regulation when there is no federal regulation, it stated that Congress cannot create such a void "subtly."[288] Merely allowing the legislation to expire without any express statement of ongoing preemption in a statute was insufficient to show clear congressional intent to preempt state price regulation.[289]

The oil companies pointed to statements in the legislative history of the law that set the final expiration date for presidential power over prices, arguing that those statements reflected a desire for a free market in oil products.[290] But the Court rejected those arguments, taking a textualist approach. It stated that legislative history statements reflecting general approval or even desire for a free market were not enough to preempt state law without any statutory text that could be interpreted as preempting state regulation in light of those statements.[291] Therefore, the Court refused to conclude that Congress intended to leave oil prices completely unregulated without express statutory text. When there is no existing federal regulation to "create an inference of preemption in an unregulated segment of an otherwise regulated field, pre-emption, if it is intended, must be explicitly stated."[292]

Similarly, the Court concluded that federal law did not implicitly preempt state regulation of wholesale electricity rates when the federal government did not regulate rates in *Arkansas Electric Cooperative Corp. v. Arkansas Public Service Commission*.[293] There, the Arkansas Public Service Commission regulated wholesale electricity rates charged by a rural power cooperative. Although the federal government generally regulated wholesale electricity rates, it did not regulate rates

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[287] *Id*. at 499.

[288] *Id*. at 500.

[289] *Id.*

[290] *Id*. at 501.

[291] *Id.* ("Without a text that can, in light of those statements, plausibly be interpreted as *prescribing* federal pre-emption, it is impossible to find a free market was mandated by federal law."). The Court distinguished its decision in *Transcontinental Pipe Line Corp. v. State Oil and Gas Board of Miss.*, 474 U.S. 409 (1986), which found Congress intended to leave certain gas purchases unregulated through its comprehensive regulation of the field.

[292] *Puerto Rico*, 485 U.S. at 504.

[293] 461 U.S. 375 (1983).

from rural power cooperatives.[294] Under Supreme Court precedent, the federal government generally had exclusive power to regulate electricity rates in wholesale markets, and Congress authorized the Federal Power Commission (now the Federal Energy Regulatory Commission) to regulate wholesale electricity rates in the Federal Power Act.[295] The Commission had concluded that it did not have jurisdiction, however, to regulate wholesale rates charged by rural power cooperatives.[296]

The Court noted that the fact that the Federal Power Commission lacked jurisdiction did not automatically mean that states could regulate prices—an authoritative federal decision that an area is "best left *un*regulated" could have preemptive effect.[297] The Court found no indication, however, that Congress intended to leave wholesale prices charged by rural power cooperatives unregulated, based on the text, history, and policy of the Federal Power Act.[298] To the contrary, Congress intended to increase regulation of wholesale rates when it passed the Federal Power Act.[299] Moreover, when the Commission concluded that it lacked jurisdiction over rural power cooperatives, it did not conclude that the best policy would be to leave their wholesale rates unregulated.[300]

The Court held that state price regulation was not implicitly preempted by the Rural Electrification Act either.[301] Power companies argued that state price regulation interfered with the purposes of the Rural Electrification Act, which authorized the Rural Electrification Administration ("REA") to provide loans to rural power cooperatives to help expand electricity access in rural areas.[302] The Court, however,

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[294] *Arkansas Elec.*, 461 U.S. at 381-82 (explaining how the Federal Power Commission (now FERC) concluded that it lacked jurisdiction to regulate wholesale rates charged by rural power cooperatives, which were supervised by the Rural Electrification Administration).

[295] *Arkansas Elec.*, 461 U.S. at 377-80.

[296] *Id*. at 383.

[297] *Id*. at 384.

[298] *Id.*

[299] *Id.*

[300] To the contrary, the agency had encouraged Congress to amend the statute to give it jurisdiction over some activities of rural power cooperatives. *Id*. at 384-85.

[301] *Arkansas Elec.*, 461 U.S. at 385 ("Nothing in the Rural Electrification Act expressly preempts state rate regulation of power cooperatives financed by the REA.").

[302] *Id*. at 385-86.

found no evidence that either Congress or the REA considered the REA's activities to preempt state rate regulation.[303] Here, the Court's analysis reflected a similar fact-specific inquiry that the Court has conducted in other cases involving obstacle preemption.[304] It observed that a particular rate might seriously interfere with federal interests, such as the ability of a power cooperative to repay its loans. A very low rate therefore might be implicitly preempted by the Rural Electrification Act.[305] It refused, however, to "assume that such a hypothetical event is so likely to occur as to preclude the setting of any rates at all."[306]

Therefore, both *Puerto Rico* and *Arkansas Electric* show that the Supreme Court has been reluctant to conclude that Congress implicitly preempted state regulation when preemption would create a regulatory void.

2. Construction of Express Preemption Clauses

Congress has at least occasionally expressly preempted state price regulation, even when there is no federal price regulation. The Airline Deregulation Act of 1978 provides one example. Before 1978, the federal government regulated airline fares.[307] In 1978, Congress decided to deregulate the airline industry, based on a determination that "maximum reliance on competitive market forces" would be the best strategy to promote efficiency.[308] In doing so, it passed an express preemption provision, which provides that States "may not enact or enforce a law…related to a price, route, or service" of an interstate air

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[303] Although the REA played a role in helping cooperatives determine rates and required cooperatives to report changes in their rates, both the legislative history of the Act and the agency's policies contemplated that the cooperatives would operate subject to state rate regulation. *Arkansas Elec.*, 461 U.S. at 387-88. The Court noted that the analysis may be different if the REA issued a valid rule finding state wholesale rate regulation to be preempted, but that was not the case. It also noted that the state public utility commission could not make any regulation that conflicted with a particular regulation promulgated by the REA. *Id.* at 388-89.

[304] *See supra* Part I.A-B, Part II.A.

[305] *Arkansas Elec.*, 461 U.S. at 389.

[306] *Id*.

[307] Morales v. Trans World Airlines, Inc., 504 U.S. 374, 378 (1992).

[308] 49 U.S.C. § 40101.

carrier.[309] The Court has recognized that this explicit language in a statute reflects a congressional determination that airfare prices are best left unregulated, therefore preempting state price regulation, even without federal price regulation.[310]

The Court has also considered whether the statute preempts state laws that affect airline prices without regulating prices directly. When doing so, the Court has considered whether the federal government has power to regulate in the area as relevant to the analysis. For example, in *Morales v. Trans World Airlines*, the Court held that the Airline Deregulation Act preempted state consumer protection laws that aimed to regulate advertisements about airfares. The Court reasoned that the state law "relate[d] to" airline rates because it had a significant impact on the fares that airlines could charge.[311] It then noted, however, that its decision did not give airlines "*carte blanche* to lie and deceive customers" because the Department of Transportation retained the power to regulate deceptive advertising that did not further competitive pricing goals.[312]

Then, in *American Airlines, Inc. v. Wolens*, the Court again considered federal regulatory power when interpreting the scope of the express preemption clause. There, the Court held that the Airline Deregulation Act did not preempt state contract law claims based on contracts between the airlines and customers, even when the contractual disputes relate to fares.[313] In reaching that conclusion, it noted that the Department of Transportation did not have authority to oversee contract disputes between airlines and their customers.[314] Therefore, even in interpreting the contours of an express preemption clause intended to create a regulatory void, the Court has considered

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[309] 49 U.S.C. § 41713(b). Congress included similar language to preempt state price regulation in the trucking industry. *See* Rowe v. New Hampshire Motor Transport Ass'n, 552 U.S. 364, 368 (2008).

[310] *See* Morales v. Trans World Airlines, Inc., 504 U.S. 374, 385-86 (1992) (reasoning that the ADA prohibits states from prescribing airline rates and enacting regulations that more broadly "relate to" rates).

[311] *Morales*, 504 U.S. at 388-90. In its statutory interpretation analysis, the Court considered ERISA preemption cases, since Congress used similar language in ERISA—highlighting the trans-substantive nature of preemption, which ultimately is a statutory interpretation analysis. *See id.* at 383-84, 388.

[312] *Id*. at 390.

[313] 513 U.S. 219 (1995).

[314] *American Airlines*, 513 U.S. at 232.

the scope of federal regulatory power when defining the bounds of the preemptive scope of the statute.

### *B. Pharmaceutical Patent Exceptionalism*

The Supreme Court's preemption decisions relating to state price regulation show a reluctance to conclude that Congress preempted state law without express statutory text when preemption would create a regulatory void. And even when there is an express preemption clause, the Supreme Court has considered the scope of federal regulatory power to interpret the preemptive scope of the statute. The Federal Circuit departed from this statutory interpretation approach in *BIO v. DC* by concluding that patent laws implicitly preempt state price regulation, without any express statutory text or any affirmative federal regulation of drug prices.

When the Federal Circuit held that the D.C. excessive price law was preempted, it created a regulatory void with respect to drug prices.[315] At the time, there was no direct federal regulation of drug prices. Nothing in the patent or FDA statutes directly regulated drug prices or empowered a federal agency to do so.[316] The federal government retained some power over drug prices through federal health insurance programs, such as by requiring rebates to Medicaid.[317] These regulations, however, were limited to drug prices within federal programs—drug prices remained generally unregulated on the private market.[318] That regulatory void continues today. Although Congress

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[315] *See* Wolitz, *supra* note 30, at 406-07 ("The United States does not have a general scheme for regulating drug prices.").

[316] March-in licenses permitted by the Bayh-Dole Act and Section 1498 could theoretically allow the government to authorize generic competitors to produce drugs as a tool to lower prices. These tools, however, have not been used much historically, and they rely on facilitating competition rather than regulating price directly. *See* Wolitz, *supra* note 30, at 406-07; Laura Dolbow, *Public Patent Powers*, 123 MICH. L. REV. 599, 615-16, 631-33 (2025).

[317] Wolitz, *supra* note 30, at 406-07.

[318] These laws also generally regulate discounts and price increases, not the price itself. Wolitz, *supra* note 30, at 406-08 ("Drug manufacturers interacting with these programs are still free to initially price their products as they wish."). The 340B program requires drug manufacturers to provide discounts to safety net healthcare providers as a condition of participating in Medicare and Medicaid, but this does not apply to the entire private market and again, regulates discounts rather than price. *See* Cong. Budget Office, *A*

recently empowered CMS to take a larger role in overseeing prices within the Medicare program, the private market remains largely unregulated.[319]

By striking down the D.C. law in its entirety, the Federal Circuit therefore created a situation where there was no drug price regulation in the private market from either the federal or D.C. government. Reaching this result without any express statutory text preempting state regulation is counter to the Supreme Court's statement in *Puerto Rico* that Congress cannot "subtly" create regulatory voids.[320]

The Federal Circuit decision also places more weight on legislative history than Supreme Court decisions. The legislative history statements from the Hatch-Waxman Act about patents allowing companies to earn greater profits are somewhat similar to the legislative history statements raised in *Puerto Rico*, which the Court stated may reflect "general congressional approval of a free market in petroleum products, or general congressional belief that such a market would result."[321] Yet unlike the Federal Circuit, the Supreme Court concluded that these "unenacted approvals, beliefs, and desires" were insufficient to find that federal law "mandated" a free market, particularly without any statutory text preempting state law.[322] Under the Supreme Court's reasoning, the legislative history statements from the Hatch-Waxman Act would likely be insufficient to show Congress mandated that drug companies operate without any price regulation. Moreover, given that Congress has never federally regulated drug prices, the inference that it intended to preempt state price regulation is even weaker than it was in *Puerto Rico* where the federal government regulated prices, then stopped.

Moreover, the Federal Circuit's failure to consider whether any federal agency had power to oversee prices and whether regulated prices were likely to interfere with federal policy goals stands in sharp contrast to the Supreme Court's reasoning in *Arkansas Electric*. In that case, the Court considered the jurisdiction of federal agencies and stated that the hypothetical potential for the government to set a very

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*Comparison of Brand-Name Drug Prices Among Selected Federal Programs* 11 (2021) (describing the 340B Drug Pricing Program).

[319] *See* Laura Dolbow, *Public Oversight of Publicly Funded Pharma*, 174 U. PA. L. REV. (forthcoming 2026) (on file with author).

[320] *See Puerto Rico*, 485 U.S. at 500.

[321] *Compare* BIO v. DC, 496 F.3d 1362, 1373 (Fed. Cir. 2007), *with Puerto Rico*, 485 U.S. at 501.

[322] *Puerto Rico*, 485 U.S. at 501.

low price was insufficient to preempt state price regulation entirely.[323] The Federal Circuit, in contrast, found that D.C. price regulation was entirely foreclosed without considering whether any federal agency had jurisdiction over drug prices or whether prices were likely to be so low as to impact innovation policy goals.[324]

Recent legislative developments cast doubt on the broad preemption of state drug price regulation as well. Just as Congress had sought to increase wholesale rate regulation in the power market generally, recent legislative efforts have generally sought to increase price regulation for patented drugs, primarily through creation of the Medicare Drug Price Negotiation Program.[325] It would be difficult to say that similar state efforts, such as Colorado's decision to set a similar price for Enbrel that CMS did in transactions unregulated by CMS, are in tension with federal policy goals.[326]

Furthermore, the Airline Deregulation Act provides an example of a situation where Congress expressly preempted state price regulation, even without authorizing federal price regulation.[327] This express preemption provides another example that weakens the inference that Congress intended to preempt state drug price regulation through silence. Yet as discussed above, the Federal Circuit did not consider the presence of express preemption clauses in other statutes in *BIO v. DC*.[328]

Therefore, the Federal Circuit interpreted patent law to create exceptionally broad insulation from price regulation for patented drugs. Without any express preemption clause or affirmative federal regulation, the Federal Circuit concluded that patent law precluded D.C. from regulating excessive prices of patented drugs. This stands in stark contrast to Supreme Court precedent, which shows a reluctance to allow Congress to implicitly create regulatory voids.

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Overall, the Supreme Court preemption cases reveal several tensions with the Federal Circuit's decision in *BIO v. DC*. The Court's

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[323] *Arkansas Elec.*, 461 U.S. at 389.

[324] *BIO v. DC*, 496 F.3d at 1374.

[325] *See Arkansas Elec.*, 461 U.S. at 384; Rai, Sachs, & Price, *supra* note 119, at 62.

[326] *See supra* notes 21-22 and accompanying text.

[327] *See supra* Part IV.A.2.

[328] *See supra* Part III.A.2.

decisions reveal substantive inconsistencies with the Federal Circuit's decision, including about the scope of patent rights,[329] federal policy goals,[330] and the power of states to make decisions that impact the balance between innovation incentives and access to medicine.[331] The Court's decisions also reveal inconsistencies in the approach to statutory interpretation, including the obstacle preemption analysis,[332] inferences from congressional silence,[333] and the relevance of federal inaction.[334] Together, Supreme Court cases involving preemption in the contexts of patent law, the pharmaceutical industry, and price regulation show that the Federal Circuit has created an exceptionalist rule for preemption with respect to pharmaceutical patents.

## V. REDUCING PHARMACEUTICAL PATENT EXCEPTIONALISM

The inconsistency of the Federal Circuit's decision in *BIO v. DC* with Supreme Court precedent leaves open the question of whether exceptionalism is problematic as a normative matter. This Part argues that preemption exceptionalism for drug patents is problematic because it limits state sovereignty and creates inconsistency in preemption jurisprudence generally. The resulting regulatory void is also

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[329] *See supra* notes 102-22 and accompanying text (discussing inconsistency with *Patterson* and *Webber* analysis about regulation of patented products).

[330] *See supra* notes 209-13 and accompanying text (discussing the Supreme Court's characterization of the Hatch Waxman Act as encouraging generic competition); *see also* notes 325-26 and accompanying text (discussing creation of the Medicare Drug Price Negotiation program).

[331] *See supra* notes 206-08 (discussing state tort claims based on drug labels permitted in *Wyeth*); *supra* notes 264-68 (discussing state power over Medicaid and PBM reimbursement permitted in *Walsh* and *Rutledge*).

[332] *See supra* notes 177-90 and accompanying text (discussing inconsistency with the Court's obstacle preemption analysis in *Kewanee*); notes 260-63 and accompanying (discussing inconsistency with obstacle preemption analysis in *Walsh* and similar preemption analysis in *Rutledge*).

[333] *See supra* notes 214-19 and accompanying text (discussing statutory interpretation analysis in *Wyeth*); notes 320-22 and accompanying text (discussing statutory interpretation analysis in *Puerto Rico*); *see also* notes 327-28 and accompanying text (highlighting express regulatory void created in the Airline Deregulation Act).

[334] *See supra* notes 220-22 and accompanying text (discussing Court's analysis of FDA action in *Wyeth*); notes 223-26 and accompanying text (discussing Court's analysis of federal action in price regulation cases).

problematic because of policy concerns about high drug prices. This Part then proposes reforms to better align patent preemption for drug patents with preemption in other areas.

### *A. Problems with Preemption*

The Federal Circuit's exceptionalist rule for drug patents is problematic, both because of harms to federalism values and harms to consistency in preemption law. Broad federal preemption of state drug price regulation harms state sovereignty—regardless of whether drug price regulation is desirable as a normative matter or not.[335] Federalism principles underlying the structure of U.S. government allow states to make independent decisions about how best to regulate within their borders pursuant to their traditional police powers.[336] State sovereignty concerns underlie the Supreme Court's generally narrow approach to federal preemption.[337]

Concerns about limits on state sovereignty are especially strong when the federal government is not actively regulating in an area. When the federal government regulates, there is some regulation of the problem perceived by state governments, and States can seek to protect their citizens by providing comments on federal policies. When the federal government preempts state law without regulating, however, it entirely forecloses the ability of states to regulate in response to market

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[335] Nash, *supra* note 271, at 1052-63; Robert Glicksman, *Nothing Is Real: Protecting the Regulatory Void Through Federal Preemption By Inaction*, 26 VA. ENVTL. L.J. 5, 21 (2008) ("The respect for state sovereignty reflected in our constitutional system of federalism supports allowing a state to regulate activities within the state's borders, even if its chosen method of regulation is ill-advised or unnecessary because of the state's mistaken diagnosis of market failure.").

[336] Nash, *supra* note 271, at 1053-54 ("The federal system created by the U.S. Constitution presupposes the legitimacy of states to regulate on a whole host of matters."); Glicksman, *supra* note 335, at 20 ("The Framers of the Constitution sought to preserve state sovereignty at the same time that they were creating a new national government.").

[337] *See, e.g.*, Medtronic v. Lohr, 518 U.S. 470, 485 (1996) ("[B]ecause the States are independent sovereigns in our federal system, we have long presumed that Congress does not cavalierly pre-empt state law causes of action.").

failures and other public health concerns.[338] Preemption also forecloses the possibility of allowing States to experiment with different regulatory approaches, which can inform debates about regulation, including whether federal regulation would be desirable.[339]

Moreover, even if the federal government concludes that regulation is not normatively justified, state governments may come to different conclusions, based on different assessments of scientific evidence, costs, and benefits.[340] Therefore, the federal government should be cautious in preempting state regulation even when the federal government chooses not to regulate. Narrowly construing statutes to limit preemption helps ensure that the federal government has made an affirmative judgment that no regulation at either the federal or state level is normatively desirable.[341]

In addition to the concerns about state sovereignty, the Federal Circuit's exceptionalist preemption rule for pharmaceutical patents is problematic because federal preemption is a trans-substantive issue. Fundamentally, federal preemption is an issue of statutory interpretation. It is problematic for courts to use different statutory interpretation approaches in different areas because it reduces the ability of States and the affected public to consistently understand the scope of federal law. Consistent statutory interpretation approaches also provide consistent rules for Congress to understand when it drafts statutes.[342] There is no reason to expect Congress to draft differently

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[338] *See* Nash, *supra* note 271, at 1055-56; Glicksman, *supra* note 335, at 20 ("If a state law is preempted as a result of the promulgation of a pollution control program by the federal government, the activities the state sought to regulate will at least be subject to some constraints other than those supplied by the market."); *id.* at 32.

[339] *See* Nash, *supra* note 271, at 1056-57; Robert Verchick & Nina Mendelson, *Preemption and Theories of Federalism* 17 in PREEMPTION CHOICE: THE THEORY, LAW, AND REALITY OF FEDERALISM'S CORE QUESTION (2009 William Buzbee, ed.).

[340] *See* Nash, *supra* note 271, at 1059-62; Glicksman, *supra* note 335, at 39-40.

[341] Congress may conclude that state regulation is normatively undesirable in situations such as when state regulation would impose externalities on other states. *See* Nash, *supra* note 271, at 1062-63; Glicksman, *supra* note 335, at 20-21.

[342] Although it is questionable whether Congress is aware of judicial statutory interpretation rules, drafters appear to be aware of at least some canons of construction. *See* Abbe Gluck & Lisa Bressman, 65 STAN. L. REV. 901 (2013).

when it drafts statutes impacting pharmaceutical patents than other statutes. Statutory interpretation is also not an area where the Federal Circuit has particular expertise, as it does with substantive patent law.[343]

### *B. Problems with a Regulatory Void*

Beyond concerns about broad preemption generally, the resulting regulatory void from *BIO v. DC* is also problematic as a policy matter. Policy concerns raised by high drug prices provide strong justifications for government intervention generally. Although federal regulation of drug prices would be preferable to create a uniform system that reduces geographic inequalities,[344] States should not be preempted from regulating drug prices where the federal government has not acted. The difficulties of the political process at the federal level mean that if state regulation of drug prices is broadly preempted, patented drug prices will likely remain largely unregulated.

Leaving drug prices entirely unregulated is normatively concerning. High drug prices make it difficult for many Americans to afford essential medicine, and those impacts are felt disproportionately by low-income and minority populations.[345] High prices also impact state budgets, as state governments typically subsidize prescription drug coverage.[346] Although the expense and risk of drug development

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[343] *See* Lee, *supra* note 35, at 1468 (arguing that specialized institutional competence should be considered when assessing whether exceptionalist rules are problematic).

[344] *See* Verchick & Mendelson, *supra* note 339, at 18.

[345] Ashley Kirzinger et al., *Public Opinion on Prescription Drugs and Their Prices*, KFF, Fig. 3 (Aug. 21, 2023); ASPE OFFICE OF HEALTH POLICY, DATA POINT: PRESCRIPTION DRUG AFFORDABILITY AMONG MEDICARE BENEFICIARIES 1, 3 (Jan. 19, 2022) ("Among adults 65 and older, Black and Latino beneficiaries are most likely to experience affordability problems."); Robin Cohen & Amy Cha, *Strategies Used by Adults with Diagnosed Diabetes to Reduce Their Prescription Drug Costs, 2017-2018*, NCHS Data Brief 1 (August 2019) ("Among adults with diagnosed diabetes, women were more likely than men to not take their medication as prescribed to reduce their prescription drug costs."); Robin Cohen & Peter Boersma, *Strategies Used by Adults Aged 65 and Older to Reduce Their Prescription Drug Costs, 2016-2017*, NCHS Data Brief 1 (May 2019) (same for adults 65 and over).

[346] *See, e.g.*, Wolitz, *supra* note 30, at 424 ("Paying for prescription medications has become an increasing share of overall state Medicaid expenditures.").

can provide justifications for high drug prices, scholars and policymakers have raised widespread concerns that high drug prices are higher than needed to incentivize development of new drugs.[347]

Patents contribute to arguments in support of government regulation. In the pharmaceutical industry, patents more often confer market power on companies than in other industries, particularly since FDA approval of generic competitors is linked to patent expiration, and health insurance often subsidizes drug purchases.[348] When a patent holder has market power, it creates a situation where the patent holder can charge monopoly prices, which can lead to affordability challenges and to economic inefficiencies such as deadweight loss.[349] Although patent law generally intends for companies to be able to charge supra-competitive prices for a limited time as a tool to encourage innovation, supra-competitive prices are not necessarily the same as monopoly prices.[350] In many industries, patents do not give patent holders the power to charge monopoly prices, either because the patent holders face direct competition or because patent holders must cross-license with others to sell a final product. In the pharmaceutical industry, however, the risk is especially high that companies will be able to charge monopoly prices on patented drugs. In other contexts where government grants of exclusivity create monopoly conditions, such as in the traditional public utility regulatory model, governments typically regulate prices.[351] Foreclosing price regulation for patented drugs takes away this long-used regulatory tool in response to concerns about potential for monopoly prices.

State regulation also has advantages because it can provide an opportunity to experiment with different price regulation models and to gather empirical evidence that may ultimately help initiate and inform

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[347] *See* Wolitz, *supra* note 30, at 404-06 (describing studies reporting high returns on investments for pharmaceutical companies).

[348] *See* Amy Kapczynski, *The Political Economy of Market Power in Pharmaceuticals*, 48 J. HEALTH POLITICS, POLICY. & LAW 215, 216 (2023).

[349] *See* Lemley, Ouellette, & Sachs, *supra* note 265, at 107-15.

[350] *See* Wolitz, *supra* note 30, at 392; *see also* Lisa Larrimore Ouellette, *IP and Access to Publicly Funded Research Results in Health Emergencies: US Policy, Law, and Practice,* WIPO Discussion Paper 1, 14 (2024) (describing the goals of innovation policy as "aligning innovation incentives with social value" and "increasing access to valuable medical technologies").

[351] *See generally* MORGAN RICKS, GANESH SITARAMAN, SHELLEY WELTON, & LEV MENAND, NETWORKS, PLATFORMS, & UTILITIES: LAW & POLICY (2022).

federal policy.[352] One often-raised objection to drug price regulation is that it would reduce the development of new drugs.[353] But without any comprehensive attempts at price regulation, it is difficult to measure how true these claims about impacts on drug development are. State-level regulation provides a way to test the impact on drug companies in smaller scale settings that could help measure impact of price regulation on incentives of drug companies and inform the best design of a federal price regulation system.

Moreover, the unjustified exceptionalism for pharmaceutical patents could lead to broader preemption challenges to other state regulations, potentially creating other regulatory voids. Because pharmaceutical patents do not operate fundamentally differently from other types of patents, the reasoning behind *BIO v. DC* could be applied to any state-level regulation that reduces the financial rewards of patent holders. In areas of traditional public utility regulation, for example, companies may have patents on aspects of products, such as electricity delivery systems and water purification systems. The broad scope of patent preemption could threaten States' ability to regulate prices in other areas as well. Moreover, Professor Shweta Kumar has argued that a broad conception of patent preemption could interfere with state right to repair laws, which require companies to sell repair parts for patented products on "fair and reasonable terms."[354]

### *C. Proposed Reforms*

Given the normative concerns with overly broad preemption of state price regulation of patented drugs, the *BIO v. DC* opinion should be overruled. Although courts could uphold state laws, such as the Colorado law establishing the Prescription Drug Affordability Board, by distinguishing those state laws from the D.C. law at issue in *BIO v. DC*, making such distinctions would not fully resolve the concerns raised by preemption exceptionalism for pharmaceutical patents.

For example, one way to distinguish the D.C. law would be to reach different conclusions for laws that apply to all excessively priced drugs, not solely patented drugs. The Colorado law, for example, allows the Board to set upper payment limits for any unaffordable drugs,

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[352] *See* Wolitz, *supra* note 30, at 457-58.

[353] *See* Michael Carrier & Genevieve Tung, *The Industry that Cries Wolf: Pharma and Innovation*, STAT (2019).

[354] Kumar, *supra* note 31, at 40.

whether they are patented or not.[355] Yet if preemption depends on whether a law targets patented drugs or not, it will invite fact-intensive disputes that will ultimately make it difficult to find state laws not preempted. Because most expensive drugs are patented, any law aiming to regulate excessive or unaffordable prices will likely predominantly apply to patented drugs.[356] Indeed, Amgen has put forth arguments that the Colorado law targets patented drugs even though it is facially neutral.[357] This sort of distinction therefore could continue to lead courts to find state laws preempted and continue to chill state-level price regulation. Furthermore, litigation costs associated with potential challenges may deter state regulation, even if a court would not ultimately find the law preempted.

Other distinctions would similarly lead to fact-intensive disputes that would ultimately make preemption difficult to avoid. Unlike the D.C. law, which was directed at the prices that manufacturers charge, the Colorado law merely regulates payments when a drug is dispensed. Given the complex supply chain for pharmaceuticals, this means the Colorado law does not directly regulate the price when drug manufacturers sell their drugs to wholesalers, as they often do.[358] The State of Colorado has argued that this feature distinguishes the Colorado law from the law at issue in *BIO v. DC* and gets around preemption.[359] Again, however, any law that regulates the ultimate payment for drugs will predictably impact the financial rewards that drug manufacturers earn—which was the central reason for preemption articulated in *BIO v. DC*.[360] Moreover, as the current presidential administration encourages more drug

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[355] *See* Colo. Rev. Stat. § 10-16-1401(23).

[356] *See* Miquel Serra-Burriel et al, *Drug Prices After Patent Expirations in High-Income Countries and Implications for Cost-Effectiveness Analysis*, JAMA (2024). Although brand-name drugs (usually covered by patents) account for only 20% of prescriptions, they account for around 80% of spending on prescription drugs in the United States. *See* ASPE OFFICE OF SCIENCE & DATA POLICY, ISSUE BRIEF: TRENDS IN PRESCRIPTION DRUG SPENDING 2016-2021 (SEPT. 2022).

[357] *See supra* note 34 and accompanying text; *see also* Wolitz, *supra* note 30, at 445 (expressing skepticism that crafting a law to cover all excessively priced drugs would be enough to avoid preemption under *BIO v. DC*).

[358] *See* Wolitz, *supra* note 30, at 453-56 (explaining distinctions between payment regulation and price regulation).

[359] *See* Defendants' Combined Cross-Motion for Summary Judgment at 25-27, Amgen v. Mizner, Case No. 24-810 (D. Colo. Aug. 9, 2024).

[360] *BIO v. DC*, 496 F.3d 1362, 1374 (Fed. Cir. 2007).

companies to sell directly to consumers, it may become increasingly difficult to avoid preemption by structuring laws to regulate payments rather than initial prices.[361]

Therefore, the breadth of the *BIO v. DC* opinion means that it will continue to threaten state drug price regulation, even if new state laws can be distinguished.[362] The better course then would be for either the Federal Circuit, Supreme Court, or Congress to overrule the decision. The inconsistency between *BIO v. DC* and Supreme Court precedent provides a straightforward rationale for doing so.

The pending litigation challenging the Colorado Prescription Drug Affordability Review Board may provide an avenue for the Federal Circuit to revisit *BIO v. DC*. Although panel decisions are binding on future panels, the court could take an appeal in the Colorado litigation en banc, either on its own motion or in response to a motion from a party, and overrule *BIO v. DC*.[363] To the extent that the Federal Circuit does not revisit *BIO v. DC*, the Supreme Court could grant certiorari and overrule the case. The exceptionalist nature of the Federal Circuit decision may help attract attention from the Supreme Court, which has shown an interest in overruling Federal Circuit decisions that make exceptionalist rules for patent law on trans-substantive issues, such as procedure, jurisdiction, and remedies.[364] Moreover, the textualist Supreme Court's growing skepticism of implied preemption and the Federal Circuit decision's reliance on legislative history may provide an additional reason for Supreme Court interest in overruling the case.[365]

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[361] *See* Dep't of Health & Human Servs., Office of Inspector General, Special Advisory Bulletin: Application of the Federal Anti-Kickback Statute to Direct-to-Consumer Prescription Drug Sales by Manufacturers to Patients With Federal Health Care Program Coverage (2026) (providing guidance about when direct-to-consumer sales are at low risk of violating federal anti-kickback laws).

[362] *See* Wolitz, *supra* note 30, at 429 ("*BIO v. DC* has seemingly had a chilling effect on state efforts to regulate excessively priced patented medications.").

[363] *See* Fed. Cir. Rule 40. The Federal Circuit could also vote to hear the case initially en banc. Fed. Cir. Rule 40(g).

[364] *See* Gugliuzza & Lemley, *supra* note 35, at 918-21; Lee, *supra* note 35, at 1425-48.

[365] *See* Rutledge v. Pharm. Care Management Ass'n, 141 S. Ct. 474, 483 (Thomas, J., concurring) (expressing skepticism of obstacle preemption generally); PhRMA v. Walsh, 123 S. Ct. 1855, 1875, 1878 (Thomas, J.,

To the extent that courts are concerned that extensive state regulation could undermine incentives for new drug development, the Supreme Court precedent described above provides guidance for preemption challenges moving forward. Overruling *BIO v. DC* would reject facial challenges to state regulation of patented drug prices. But it could leave room for preemption in applied contexts, such as if a price is set so low that it clearly interferes with innovation incentives. The Supreme Court consistently left room for the possibility of as-applied challenges, such as when it stated that a very low price for wholesale power might interfere with federal interests in *Arkansas Electric*.[366] Affirmative federal regulation, such as Medicare price negotiation, could also preempt state regulation in the contexts where the federal government regulates price. Furthermore, although States have broad police powers, courts can consider whether state regulations fall within the scope of state police powers and whether regulations violate the dormant Commerce Clause.

If the courts do not overrule *BIO v. DC*, Congress should step in and abrogate the decision. Express statutory language could overrule the case and provide guidance for States moving forward. Although legislation is difficult to pass, particularly with the filibuster in the Senate, a legislative amendment could gain support. There is widespread bipartisan support for increased regulation of drug prices.[367] In recent years, moderate drug pricing legislation has passed, such as the Inflation Reduction Act, which established the Medicare Drug Price Negotiation Program.[368] Moreover, a legislative amendment that punts the ultimate issue to state governments might not face the

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concurring) (same); Wyeth v. Levine, 129 S. Ct. 1187, 1211 (2009) (Thomas, J., concurring) ("This Court's entire body of 'purposes and objectives' pre-emption jurisprudence … improperly rely on legislative history, broad atextual notions of congressional purpose, and even congressional inaction in order to pre-empt state law.").

[366] *Arkansas Elec.*, 461 U.S. at 389. Precedent about when rate regulation becomes "confiscatory" and amounts to a taking could provide guidance for when very low prices might pose an obstacle to innovation policy goals. *See* Fed. Power Comm'n v. Hope Nat. Gas, 320 U.S. 591 (1944); Railroad Commission Cases, 116 U.S. 307, 331 (1886); Smyth v. Ames, 169 U.S. 466, 546–47 (1898).

[367] *See, e.g.*, *Senate Judiciary Committee Advances Six Bipartisan Bills to Lower Prescription Drug Prices* (April 3, 2025), https://www.durbin.senate.gov/newsroom/press-releases/senate-judiciary-committee-advances-six-bipartisan-bills-to-lower-prescription-drug-prices.

[368] *See* Pub. L. 117-169, Secs. 1191-98 (Aug. 16, 2022).

same political obstacles as a federal law that seeks to regulate prices directly.[369] Alternatively, Congress should continue to consider ways to increase drug price regulation at the federal level. In this situation, it could consider expressly preempting state drug price regulation that conflicted with affirmative federal price regulation.

## CONCLUSION

In *BIO v. DC*, the Federal Circuit broadly held that patent law preempts state price regulation of patented drugs. The decision was based on a broad inference of congressional intent, untethered to statutory text. It further assumed that any impact on federal policy goals were sufficient to preempt state price regulation, without any consideration of how the law might be implemented in practice or the likely magnitude of the impact on innovation policy goals.

This decision creates an exceptionally broad zone of federal preemption surrounding patented drug prices that is inconsistent with Supreme Court precedent. The decision is not just inconsistent with Supreme Court precedent about the preemptive scope of federal patent law, but also inconsistent with Supreme Court precedent about federal preemption in the pharmaceutical industry and of state price regulation. Given the lack of federal regulation of drug prices, the Federal Circuit has created an exceptionally broad insulation from price regulation for patented drugs.

The exceptionalist rule for pharmaceutical patents is problematic because it harms state sovereignty, creates inconsistent precedent in a trans-substantive area of law, and leaves drug prices without any direct regulatory oversight, despite legitimate concerns about excessive prices. Courts or Congress should therefore overrule *BIO v. DC*.

[369] *See* Wolitz, *supra* note 30, at 441-42.