



States' Rights: A Patent Law Analysis of NASHP Rate-Setting Model Act

*Robin Feldman, Betty Chang Rowe, Rabiah Oral, Amy Y. Gu,
and Katherine Gudiksen¹*

Introduction

We have been asked to set out the argument that a state's rights under the Tenth Amendment of the US Constitution gives a state the power to enact provisions such as the National Academy for State Health Policy's (NASHP) Drug Payment Rate Regulation Model Act, notwithstanding federal patent law. Accordingly, this white paper addresses issues of federalism, preemption, and the Takings Clause as they relate to the intersection of patent law and state drug rate-setting legislation.

This paper proceeds in three parts. Part I provides general background on the preemption doctrine as it applies to state regulation of areas that involve patents. Part II describes the three levels of preemption and applies those levels to state regulation of drug payment rates. Part III examines whether state regulation of drug payments would rise to the level of a regulatory taking under the takings clause of the Fifth Amendment of the US Constitution. Part IV provides existing examples of state regulation of health care rates. In addition, this section considers the issue of the state in its role as a commercial payer in the marketplace.

Part I: States' Rights in the Federal System

Under our federal system, states draw their power from the Tenth Amendment of the US Constitution, which reserves to the states all power not specifically granted to the federal government nor forbidden by the Constitution.² The modern approach to the relationship between states and the federal government is one of concurrent and overlapping powers, with numerous state and federal regulatory programs existing in parallel. Examples run the gamut, from banking which operates under a dual system in which chartering taking place at either the national or state level, to federal and state taxation schemes, to securities law in which states are able to impose additional notice requirements on the sale of securities, to the joint federal and state Medicaid program in the health care realm.³ As a general matter, overlapping and concurrent powers are the norm, even when the federal government has staked out considerable territory.

Within this context, one cannot overemphasize the importance of a state's ability to respond to the needs of its local citizenry. The importance of local interests has a long and hallowed history in constitutional jurisprudence, and states are considered to be on the frontlines of government "by the people." Given that law frequently involves settling the problems of people living together, such problems are likely to appear at the level of everyday life, close to local leadership and far from the hallways of the federal government.⁴ Thus, states are considered particularly sensitive to, and particularly entitled to respond to, the needs of the population as those needs vary across different localities.

Moreover, a state's ability to respond to the needs of its local citizenry is considered essential for securing the trust of the local electorate -- and without that trust, states cannot play their proper role in maintaining the balance of power. Thus, "the 'political safeguards of federalism . . . depend on the states

retaining important regulatory responsibilities and government functions that touch the daily lives of their citizens.”⁵ In short, preemption must be cabined with particular care lest it threaten to “cut off state access to the wellsprings of popular support.”⁶

Without a doubt, patent law is a federal scheme that governs issues of grants, validity, and infringement of a patents as well as procedures to challenge a patent. Notwithstanding this federal framework, states retain the ability to regulate traditional areas of state concern even if patents are somehow involved in these arenas. That a patent happens to be implicated in a certain issue does not automatically strip states of their core rights to regulate health, commerce, contract and other areas of state concern within their borders. For instance, states have the authority to regulate commercial contracts involving patents, deceptive practices involving patents, and in some cases, unfair competition involving patents.⁷ Similarly, as part of their core rights, states have broad tax authority and may regularly tax products that implicate patents. *See, e.g., Webber v. Virginia*, 103 U.S. 344, 347-48 (1880) (finding state tax not preempted as applied to the sale of patented products). And in the area of health care, a state may directly regulate matters relating to health and safety of its citizenry as part of its general police power. *See Hillsborough County v. Automated Med. Lab., Inc.*, 471 U.S. 707, 714 (1985) (noting that statutes regulating health and safety are part of a state’s general police power, and that there is a strong presumption such statutes are not preempted by federal laws). Moreover, states promulgate their own tax rules and regulations, including rules on exclusions, deductions and exemptions. By including health care expenditures in such rules, states already indirectly regulate the costs of health care. To put it simply, a state does not become impotent whenever a regulation would involve products that might be subject to a patent.

Understanding the interplay between federal and state power related to patents also requires an understanding of the commercial and economic context in which patent rights exist. The granting of patents in the federal Patent Act relies upon and presupposes a functioning state system of commerce and contract law. Commerce, contract and consumer laws traditionally are viewed as appropriate forums for reflecting and promoting local values and preferences, and as such, appropriate areas for state regulation.⁸ State law cannot be entirely displaced simply because a particular commercial behavior relates to patents. In sum, as a general matter, the presence of patented products should not act to cut off a state’s power in its traditional areas of activity.

Part II: Three Levels of Preemption and Drug Payment Rate Regulation

In the modern context of overlapping powers, the doctrine of federal preemption manages the areas of overlap, delineating those areas in which state power is constrained by federal activity. Preemption generally comes in three forms: express, field and conflict. For express preemption, Congress must particularly specify that it is exercising authority to preempt state law. In contrast, with field preemption, federal law may preempt state law if the “federal regulation [is] so pervasive as to make reasonable the inference that Congress left no room to supplement it.”⁹ Field preemption occurs when Congress “intended to foreclose any state regulation in the area, irrespective of whether state law is consistent or inconsistent with federal standards.” *Oneok v. Learjet*, 135 S. Ct. 1591, 1595 (2015) (internal citation marks omitted). Finally, with conflict preemption, either “compliance with both federal and state regulations is a physical impossibility” or “state law ‘stands as an obstacle to the accomplishment and execution’” of the federal scheme. *Id.* The following section examines drug payment rate regulation under the lens of each form of preemption.

Express preemption: The Patent Act does not expressly preempt drug payment rate regulation. As the Federal Circuit noted in 2007, “there is no express provision in the patent statute that prohibits states from regulating the price of patented goods.” *Biotechnology Industry Org. v. District of Columbia*, 496 F.3d 1362, 1372 (Fed. Cir. 2007). In the same vein, Judge Dyk in his dissent in the denial of an *en banc* hearing petition in *Biotechnology*, pointed out “[t]here is not a word in the cited legislative history of the Hatch-Waxman Act suggesting any concern about state price regulation of patented pharmaceutical products.” *Biotechnology Industry Org. v. District of Columbia*, 505 F.3d 1343, 1351 (Fed. Cir. 2007) (Dyk, J., dissenting). Quite simply, express preemption is not a concern here.

Field preemption: Nor is it likely that field preemption exists. The Patent Act does not regulate the price for any patented product. It does not guarantee or entitle a profit to the inventor at all, and most patent holders never garner any returns from their invention. Although patent holders are free to completely withhold their invention from the market,¹⁰ for those who do choose to sell a product based on that patent, the Patent Act does not guarantee any particular level of profit, and certainly not at the level of a monopolist. In fact, the Supreme Court has held that given the language of the Patent Act, Congress could not have intended “the mere existence of a patent to constitute . . . market power.”¹¹ In short, patent laws do not touch the issue of pricing or level of return in any manner.

In addition, the very existence of the federal 340B program demonstrates that Congress did *not* intend to foreclose government regulation of the price of a patented product, including patented drugs, through the Patent Act. Born from a concern over increasing pharmaceutical prices, the federal 340B program requires pharmaceutical manufacturers that participate in Medicaid to provide discounted prices on covered outpatient drugs to health care facilities that serve vulnerable patient populations. Moreover, Congress continues to consider additional measures that address drug pricing, including the 2017 Improving Access to Affordable Prescription Drugs Act, which was introduced in the Senate on March 29, 2017.

Congress would not have established the 340B program or continue to consider proposed drug pricing related legislation if it believed that the Patent Act occupies the area of drug pricing as to foreclose any further regulation. Far from the “pervasive” regulation needed for field preemption, the Patent Act does not regulate the price of patented products, including pharmaceuticals, at all.

Conflict preemption: Lastly, conflict preemption is dubious as well. The first brand of conflict preemption, the “impossibility” type, is inapplicable given that one could comply with the Model Act and the Patent Act simultaneously. As explained above, the Patent Act contains no provision regulating the price of pharmaceutical drugs and therefore, no impossibility exists.

The “obstacle” type of conflict preemption appears to be the path most often taken by the Supreme Court (although consistently criticized by Justice Thomas) in analyzing preemption matters,¹² and the type that could present an issue here. The salient question would be whether the governmental setting of the cost or payment rate for a drug stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress via the Patent Act.

We begin with “the presumption that state and local regulation related to matters of health and safety can normally coexist with federal regulations.” *Hillsborough County, Florida v. Automated Med. Labs., Inc.*, 471 U.S. 707, 718 (1985).¹³ Moreover, governmental drug rate setting does not conflict with patent holder rights. The only right conferred upon a patent holder under the Patent Act is the right to “exclude others from making, using, offering for sale, or selling the invention” for a limited time period.¹⁴ 35 U.S.C.

§ 154(a). The patent holder has no rights under patent law other than this limited exclusionary right.¹⁵ In other words, despite popular misconception, or at least much sloppy language, a patent confers no affirmative rights at all, but merely the negative right to exclude.¹⁶ A corollary to the limited nature of a patent grant is the notion that the Patent Act does not guarantee or entitle a minimum, maximum, or any profit to the patent holder.

One should note that the Federal Circuit tends to use rather expansive language, emphasizing pecuniary rewards as stemming from a patent holder's exclusionary right.¹⁷ In contrast, the Supreme Court teaches that "[i]t is the *public* interest which is dominant in the patent system" and that a "patent is a privilege," one "conditioned by a *public* purpose."¹⁸ Thus, while private pecuniary reward is a carrot, under Supreme Court precedent, economic reward is not the fundamental objective of patent law and is subservient to the public interest.¹⁹ In this respect, drug payment rate regulation should not adversely affect the patent holder's rights under patent law.

The arguments advanced in the section above on field preemption related to the federal 340B program would apply to the issue of conflict preemption as well. How could Congress have established a program mandating discounted prices for drugs under certain circumstances if drug payment regulation would "stand as an obstacle to the accomplishment and execution" of the Patent Act?

Although the lines of arguments described so far should be sufficient to demonstrate lack of conflict preemption, other potential arguments also exist. For example, it cannot be true that any rate regulation involving products subject to a patent would conflict with the Patent Act. When governments regulate rates in any arena, the limitation on returns, by necessity, affects returns for the individual products involved in the activity, including products subject to a patent. For example, state and federal governments for decades have engaged in rate regulation related to the delivery of electricity, an activity that undoubtedly involves numerous products subject to patent rights. Similarly, when states regulate rates for a particular hospital procedure, examples of which are described in section IV below, that regulation necessarily implicates the potential returns to those who produce the inputs to those procedures, many of which are undoubtedly subject to patents. The Patent Act cannot be so breathtakingly expansive that governmental hands are tied to such an extent.

Significantly, to minimize the risk of preemption under the obstacle approach, a state's drug rate-setting laws should be generally applicable to both patented and non-patented drugs. State legislation should be not aimed at or limited only to patented drugs. In *Biotechnology Indus. Org. v. District of Columbia*, 496 F.3d 1362 (Fed. Cir. 2007), the Federal Circuit held that a Washington, DC, law prohibiting the sale of any patented drug at an "excessive price" was preempted by federal patent law because the law "stands as an obstacle to the federal patent law's balance of objectives as established by Congress." 496 F.3d at 1374. The court reasoned that by penalizing high drug prices, the District was "limiting the full exercise of the exclusionary power that derives from a patent"²⁰ and seeking "to re-balance the statutory framework of rewards and incentives insofar as it relates to inventive new drugs." *Id.* The holding hinged on the fact that the law in question "is in no way general, affecting only patented products." *Id.* at 1373; *see also id.* at 1374 ("The fact that the Act is targeted at the patent right is apparent on its face. It applies only to patented drugs.") By regulating only the price of patented drugs, "[t]he District has ... seen fit to change federal patent policy within its borders" because the law's "effect is to shift the benefits of a patented invention from inventors to consumers." *Id.* at 1374.

The *Biotechnology* case should not be a barrier to the Model Act because the Model Act, unlike the Washington, DC, law, applies to both brand name and generic prescription drugs. *Biotechnology* does

not reach those circumstances. In denying a petition for an *en banc* hearing, the Federal Circuit expressly limited its decision to the facts of that case.²¹ The court also cautioned that interpreting the case as “requir[ing] the preemption of ‘any state law regulating the prices of patented pharmaceutical products’” would “overstate the breadth of the panel opinion.”²²

It is not possible to predict how the courts will rule on an issue, and the constitutionality of state regulation of pricing rates for drugs (patented or unpatented) is largely uncharted territory.²³ In particular, the Federal Circuit is a notoriously pro-patent holder venue, tending to take an expansive view of the Patent Act and of patent holder rights. In contrast, the Supreme Court consistently reins in the Federal Circuit’s expansive views of patent law. Despite these uncertainties, the Model Act appears to be on solid footing to withstand federalism concerns in relation to the Patent Act insofar as the Model Act does not target only patented pharmaceuticals and does not deprive the patent holder of the benefits of its exclusionary right.²⁴

Part III: Regulatory Takings under the Fifth Amendment

The Fifth Amendment of the US Constitution protects property owners against government “takings” of private property without just compensation.²⁵ A traditional taking is possessory (physical) in nature, in which the government condemns private property, takes physical possession, and offers just compensation to the private owner. The Takings Clause has been extended to “regulatory takings,” in which government regulations are “so onerous that its affect is tantamount to a direct appropriation or ouster.” *Lingle v. Chevron U.S.A., Inc.*, 544 U.S. 528, 537 (2005). Under the seminal regulatory takings case of *Pennsylvania Coal Co. v. Mahon*, if a regulation “goes too far it will be recognized as a taking.” 260 U.S. 393, 415 (1922).

A threshold issue exists as to whether patent rights constitute core property rights such that they come within the purview of the Takings Clause. However, from a constitutional perspective, the respect for real property evidenced in constitutional language and history is worlds apart from what is reflected in the Constitution’s intellectual property clause.²⁶ Rather, the intellectual property clause gives Congress the power to grant rights for limited times in pursuit of a specific goal. This creation of a narrow public franchise for limited policy reasons stands in sharp contrast to the Framers’ conception of core private property rights, and the way in which those rights are treated in the Constitution.²⁷

Moreover, courts have not applied the takings clause to patents. In the words of one scholar—one who actually advocates applying the takings clause to patents, “modern courts and scholars . . . seem to agree in a rare case of unanimity that the historical record reflects no instance of a federal court holding that the Takings Clause applies to patents.”²⁸

The Supreme Court cases contemplating patents in the context of takings generally have involved the extent to which the government can claim sovereign immunity protection if patent holders sue the government or government contractors for patent infringement. Specifically, since 1888, those cases have rejected the notion that patents should be treated as property for takings purposes.²⁹

However, the question of whether patent rights might be subject to the Fifth Amendment is implicated in a case currently before the Supreme Court, *Oil States Energy Serv., LLC v. Greene’s Energy Group, LLC, et al.*, Docket No. 16-00712 (U.S. Nov. 29, 2016). Oil States raises the issue of whether the Patent & Trademark Office’s inter-partes review procedure violates the Constitution by extinguishing private

property rights through a non-Article III forum without a jury. The court held oral argument on Nov. 27, 2017, and a decision is expected in 2018. Given the pending case it is worth examining the contours of a regulatory takings argument in relation to the Model Act.

As noted, the seminal regulatory takings case of *Pennsylvania Coal* held that if a regulation “goes too far it will be recognized as a taking.” In the near century since *Pennsylvania Coal*, the Supreme Court has not formulated definitive rules on when a regulation “goes too far” such that it constitutes a regulatory taking. This area of law has been characterized by “ad hoc, factual inquiries, designed to allow careful examination and weighing of all the relevant circumstances.” *Tahoe-Sierra Pres. Council, Inc. v. Tahoe Reg'l Planning Agency*, 535 U.S. 302, 322 (2002). A two-tier inquiry, however, has emerged.

The first step is to determine whether the regulation deprives the owner of “all economically beneficial or productive use” of the property. A regulation that denies “all economically beneficial or productive use” of the property “will require compensation under the Takings Clause.” *Murr v. Wisconsin*, 137 S. Ct. 1933, 1942 (2017) (quoting *Palazzolo v. Rhode Island*, 533 U.S. 606, 617 (2001)); see also *Lucas v. South Carolina Coastal Council*, 505 U.S. 1003, 1015 (1992). The Supreme Court has taken a strict view of regulatory takings, for example, finding that a regulation eliminating more than 90 percent of the appraised value of a land parcel did not constitute a regulatory taking, see *Palazzolo*, 533 U.S. at 616, nor did a moratorium on all land development for almost three years. See *Tahoe-Sierra*, 535 U.S. at 341-42. Here, a federal or state regulation setting the price of a drug below list price would not deprive the drug manufacturer of “all” economic benefit given that the manufacturer can still obtain a return on the sale of the drug, and likely a substantial one. Moreover, if the regulated price were at a level that ensured the volume of drug sold would generate revenue equal to (or greater than) that generated at the previous price with less volume, there would be no taking whatsoever because the manufacturer lost no economic benefit.

Where, as here, a regulation falls short of eliminating all economically beneficial use, a regulatory taking may still exist, “depending on a complex of factors.” *Palazzolo*, 533 U.S. at 617; see also *Murr*, 137 S. Ct. at 1943. The “complex of factors” considered in this second step include (1) the economic impact of the regulation on the claimant; (2) the extent to which the regulation has interfered with distinct investment-backed expectations; and (3) the character of the governmental action. *Penn Cent. Transp. Co. v. City of New York*, 438 U.S. 104, 124 (1978).

These factors embody the balancing of two competing objectives central to regulatory taking doctrine: the individual's right to retain and exercise rights at the core of private property ownership and the government's “well-established” power to “adjust rights for the public good.” *Murr*, 137 S. Ct. at 1942 (citations omitted). To avoid a constitutional regulatory takings challenge, any governmental drug-rate setting scheme should take into account these factors and underlying objectives. Ultimately, the “goal is usually to determine how the challenged regulation affects the property's value to the owner.” *Id.* at 1944.³⁰ And “[i]n all instances, the analysis must be driven by the purpose of the Takings Clause, which is to prevent the government from ‘forcing some people alone to bear public burdens which, in all fairness and justice, should be borne by the public as a whole.’” *Murr*, 137 S. Ct. at 1943 (citations omitted). Finally, as noted above, modern court findings of regulatory takings are rare and would be particularly unusual in the context of a healthy return for the party claiming that property has been taken.

Part IV: Examples of State Regulation of Health Care Rates

Across the nation, state legislatures are considering, and some have passed, legislation aimed at reducing drug prices and/or increasing transparency and reporting matters. One recent study indicates that in 2017, more than 80 pharmaceutical pricing bills were proposed in over 30 states nationwide.³¹ In particular, Georgia enacted SB 200, which mandates that health benefit plans apply a prorated daily cost-sharing rate to prescriptions that are dispensed in certain circumstances.³² New York also recently enacted a budget bill authorizing the state to identify high-cost drugs, set a value price, and demand additional rebates from branded manufacturers when Medicaid expenditures on the drugs exceed a certain threshold from the targeted price.³³

States have engaged in general rate setting for health care for decades. An overview of health care rate setting at the state level shows three forms of programs: all-payer rate-setting programs, state Medicaid programs, and reference pricing systems as payors.

All-Payer Rate-Setting Programs: In the 1970s and early 1980s, several states, including Connecticut, Maryland, Massachusetts, New Jersey, New York, Washington, and West Virginia enacted legislation that established programs that set maximum rates for procedures for all hospitals. With increasing emphasis on managed care and competition, five of the seven states had ended these programs by 1996.³⁴ Today, Maryland still runs an active all-payer rate setting system, but has recently shifted its hospital rate-setting system to global budgets -- those encompassing broad ranges of activities or providers that are copied by other states, including Massachusetts, Pennsylvania, and Vermont's all-payer accountable care organization.³⁵ Other examples include West Virginia, which has a rate-setting system that is administered by the West Virginia Health Care Authority and applies only to private, nongovernmental payers.³⁶ Colorado legislation SB 10-020 enacted in 2010 authorizes CoverColorado, the state's high-risk pool for the uninsured, to set its own health provider reimbursement rates instead of paying commercial rates.³⁷ In addition, Rhode Island empowers regulators to cap hospital price increases in connection with the state's review of managed care contracts.³⁸

State Medicaid Programs: Medicaid is a federally-funded program administered by each individual state. Many states set limits on prescription reimbursement, which are often based on average wholesale price. While the program provides a federal upper limit (FUL), states have the option to develop their own Maximum Allowable Cost (MAC) programs for multiple-source drugs. Compared to the federally-administered limit, state MAC programs give states greater flexibility in determining which drugs to include in the program and in setting the reimbursement rates. States are thus able to set lower reimbursement amounts for more multiple-source drugs than are included in the FUL program.³⁹ Forty-five states utilized MAC programs as of Jan. 1, 2012.⁴⁰

Reference Pricing Systems: Similar to the Medicaid MAC programs, states, in their capacity as payers have used reference pricing to create price limits. The most successful and well-known case of reference pricing used to set health care rates is the CalPERS program. The program began in 2011 and set standard prices for knee and hip replacements. It required members to pay any charges beyond that price.⁴¹ Since then, CalPERS has extended the program to cataract surgery, colonoscopies, and arthroscopic knee surgery.

The State in Its Role as Commercial Payer in the Marketplace

As discussed above, the regulation of health care generally and of the price of goods and services involving patents specifically is a shared federal and state activity. A state's right to set drug rates is even stronger in its role as a payer of health care in the commercial market. As with any entity in the marketplace, a state can decide what it will purchase at what price. As with any entity, a state has the authority to establish its budget and contract for services required to run its programs. For example, a state unquestionably may decide how much it will pay for a desk or for pencils for its educational system, even though both products involve patents. That the products purchased are for a state's health care system should make no difference.

As a payer of health care, states already determine how much they are willing to pay for products necessary for their health care system. Such products include those that are non-medical in nature, for example, the beds, tables, computer monitors, pillows and cleaning supplies in state medical facilities. They also include those medical in nature, such as the cost of thermometers, blood pressure monitors, and needles as well as the cost a hip or knee replacement or cataract surgery. *See, e.g.*, CalPERS program. Patents are implicated in all of these products, yet their existence does not defeat a state's right to determine what it will buy and for how much.

This reasoning applies to patented pharmaceuticals. A hip replacement procedure, for example, necessarily involves the administration of various drugs. Subsumed in the state's standard aggregate price for a hip replacement is the price of those drugs, thus, states in their capacity as payers indirectly set drug prices in this manner.

This is not to suggest that the state has an insufficient interest in drug payment rate regulation outside the context of the state's role as a commercial payer. We simply note that to the extent a state is justified in engaging in health care drug payment rate regulation in general, how much more so is it justified when acting as a commercial payer.

Conclusion

Intelligent minds could differ on the policies embedded in various state provisions that could be enacted. In addition, although there are no directly controlling decisions, one cannot know with certainty what the courts will decide. Nevertheless, under traditional federalism analysis, the Patent Act should not preempt state health care regulation of drug payment rates, in general, and certainly not for the state in its role as a commercial payer in the marketplace.

Notes

This brief was made possible with support from the Laura and John Arnold Foundation and was produced by the Center for State Rx Drug Pricing, a project of the National Academy for State Health Policy, an independent academy of state healthpolicymakers working together to identify emerging issues, develop policy solutions, and improve state health policy and practice. The center contracted with the Institute for Innovation Law at the University of California Hastings College of the Law to develop this white paper. Thanks to Robin Feldman, Betty Chang Rowe, Rabiah Oral, Amy Y. Gu, and Katherine Gudiksen for sharing their expertise.

1. Robin Feldman, Harry and Lillian Hastings Professor of Law and Director of the Institute for Innovation Law, University of California Hastings College of the Law; Betty Chang Rowe, Affiliated Scholar, University of California Hastings College of the Law; Rabiah Oral, Research Fellow, Institute for Innovation Law, University of California Hastings College of the Law; Amy Y. Gu, Managing Editor, UCSF/UC Hastings Consortium on Law, Science & Health Policy; and Katherine Gudiksen, Senior Research Fellow, UCSF/UC Hastings Consortium on Law, Science & Health Policy. Portions of this White Paper are based on the following academic article: Robin Feldman, *Federalism, First Amendment & Patents: The Fraud Fallacy*, 17 COLUMBIA SCIENCE & TECH. L. REV. 30 (Fall 2015). For expanded analysis of these issues, see *id.* Portions of the takings discussion are based on the following draft work: Robin Feldman, *May Your Drug Price Be Ever Green*, available at https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3061567
2. Preemption flows from the Supremacy Clause of the Constitution, which holds that “[t]he Constitution, and the Laws of the United States which shall be made in pursuance thereof...shall be the supreme law of the land; and the judges in every state shall be bound thereby, anything in the constitution or laws of any state to the contrary notwithstanding.” U.S. CONST., art. VI, cl. 2.
3. See U.S. CONST. amend. X.
4. Henry M. Hart, Jr., *The Relationship Between State and Federal Law*, 54 Colum. L. Rev. 489, 489 (1954) (noting that the “the law begins and has to begin at the grass roots”).
5. Ernest A. Young, “*The Ordinary Diet of the Law*”: *The Presumption Against Preemption in the Roberts Court*, 2011 SUP. CT. REV. 253, 263.
6. *Id.* at 264.
7. See Robin Feldman, *Federalism, First Amendment & Patents: The Fraud Fallacy*, 17 COLUMBIA SCIENCE & TECH. L. REV. 30 (Fall 2015).
8. For expanded exploration of this topic, see *id.*
9. *PG&E v. State Energy Res. Conservation & Dev. Comm’n*, 461 U.S. 190, 204 (1983) (citing *Fid. Fed. Sav. & Loan Ass’n v. de la Cuesta*, 458 U.S. 141, 152 (1982)).
10. See 35 U.S.C. § 271(d)(4) (2000) (stating that “[n]o patent owner otherwise entitled to relief for infringement or contributory infringement of a patent shall be denied relief or deemed guilty of misuse or illegal extension of the patent right by reason of his having...refused to license or use any rights to the patent”).
11. See *Ill. Tool Works Inc. v. Indep. Ink, Inc.*, 547 U.S. 28, 42 (2006) (holding in the context of a tying allegation that the presence of a patent does not give rise to a presumption of market power).
12. See Robin Feldman, *Federalism, First Amendment & Patents: The Fraud Fallacy*, 17 COLUMBIA SCIENCE & TECH. L. REV. 30, 75 (Fall 2015).
13. As a general matter, a presumption against preemption of state activity exists when Congress has legislated in an area that the states have traditionally occupied. See *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218 (1947).
14. See also *Dawson Chemical Co. v. Rohm and Haas Co.*, 448 U.S. 176, 215 (1980) (“the essence of a patent grant is the right to exclude others from profiting by the patented invention”).
15. See *Bloomer v. McQuewan*, 55 U.S. 539, 549 (1852) (“The franchise which the patent grants, consists altogether in the right to exclude every one from making, using, or vending the thing patented, without the permission of the patentee. This is all that he obtains by the patent.”).
16. See ROBIN FELDMAN, *RETHINKING PATENT RIGHTS* 24 (Harvard 2012) (discussing the Patent Act’s right to exclude, in contrast with affirmative rights).
17. See, e.g., *Sanofi-Synthelabo v. Apotex, Inc.*, 470 F.3d 1368, 1383 (Fed. Cir. 2006) (“the encouragement of investment-based risk is the fundamental purpose of the patent grant, and is based directly on the right to exclude. . . the patent system provides incentive to the innovative drug companies to continue costly development efforts”) (citations omitted); *King Instruments Corp. v. Perego*, 65 F.3d 941, 950 (Fed. Cir. 1995) (“The patent owner expends resources in expectation of receiving this [economic] reward” during the exclusivity period).
18. *Mercoïd Corp. v. Mid-Continent Inv. Co.*, 320 U.S. 661, 665 (1944) (emphasis added).
19. See, e.g., *Motion Picture Patents Co. v. Universal Film Mfg. Co.*, 243 U.S. 502, 511 (1917) (since 1829, “this court has consistently held that the primary purpose of our patent laws is not the creation of private fortunes for the owners of patents, but is ‘to promote the progress of science and the useful arts’”); *Kendall v. Winsor*, 62 U.S. 322, 327-28 (1858) (“It is undeniably true, that the limited and temporary monopoly granted to inventors was never designed for their exclusive profit or advantage; the benefit to the public or community at large was another and doubtless the primary object in granting and securing that monopoly.”).
20. Specifically, the Federal Circuit found that the District of Columbia law “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.” *Biotechnology*, 496 F.3d at 1374. In a strong dissent on the panel’s denial of an en banc hearing petition, Judge Dyk rejected the majority’s pecuniary reward rationale, pointing out that “[a] patent grant is designed not to allow the patent holder exploit the grant for the maximum profit that the market will bear, but merely to confer a right of exclusivity. The panel’s assertion to the contrary is inconsistent with longstanding Supreme Court precedent.” *Biotechnology*, 505 F.3d at 1350.

21. *Biotechnology*, 505 F.3d at 1348 (“The panel opinion’s analysis rests...on the specifics of the D.C. statute, considered as a whole.”).
22. *Id.*; see also Lipski, *Excessive Pricing*, 39 U. TOL. L. REV. at 935 (*Biotechnology*’s preemption holding “is correct because it specifically targeted patented pharmaceuticals and not all pharmaceuticals, but only if construed narrowly. If however, the holding is construed to mean that all price controls on patented products are preempted by the federal patent statute, the court’s holding may reach too far.”).
23. See *Biotechnology*, 505 F.3d at 1348 (“Whether future efforts of states to regulate drug prices, which for example did not only target patent drugs or did not as significantly or directly undermine the balance of the federal patent right, would also be preempted is a question that remains for another day.”).
24. While the issue of federalism outside of the Patent Act is not within the scope of our engagement, our research suggested that the Employee Retirement Income Security Act of 1974 (ERISA) might pose an issue to the Model Act. Earlier this year, the United States Court of Appeals for the Eight Circuit held that ERISA expressly preempts a section of the Iowa Code that regulates generic drug pricing by pharmacy benefits manager and that requires certain disclosures of drug pricing methodology. See *Pharm. Care Mgmt. Ass’n v. Gerhart*, 852 F.3d 722 (8th Cir. 2017). At least one federal district court has followed the Eighth Circuit (see *Pharm. Care Mgmt. Ass’n v. Rutledge*, 240 F.Supp.3d 951, 957-59 (E.D. Ark. 2017) (Arkansas statute regulating how pharmacy benefits managers set reimbursement rates on generic drug prescription was preempted by ERISA)). On the flip side, at least one commentator has questioned the Eight Circuit Gerhart decision. See John L. Utz, *Preemption Made (Too) Easy: Pharmaceutical Care Management Ass’n v. Gerhart*, 25 No. 2 ERISA LIT. REP. NL2 (May 2017). Undoubtedly, more development of the law lies ahead and this is not our area of expertise. Nevertheless, it is our general understanding that states may wish to consider crafting state rate-setting provisions as insurance regulations to invoke the savings clause of ERISA and minimize any preemption concerns.
25. U.S. CONST. amend. V (“[N]or shall private property be taken for public use, without just compensation.”).
26. See *Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 848 n.2 (2015) (Thomas J., dissenting (“The Anglo-American legal tradition has long distinguished between “core” private rights—including the traditional property rights represented by deeds—and other types of rights.”)
27. See *id.* (the Framers adopted a scheme in which intellectual property rights are “privileges or franchise . . . created purely for reasons of public policy and which have no counterpart in the Lockean state of nature”); see also Robin Feldman, *Federalism, First Amendment & Patents: The Fraud Fallacy*, 17 COLUMBIA SCIENCE & TECH. L. REV. 30, 72 (Fall 2015).
28. See Adam Mossoff, *Patents as Constitutional Private Property: The Historical Protection of Patents Under the Takings Clause*, 87 B.U.L. REV. 689, 691 (2007).
29. See *id.* at 701-710, 711-715 (criticizing these Supreme Court decisions by referencing earlier Supreme Court and lower courts cases from the 1870s, as well as by arguing against those who view passage of sovereign immunity legislation in 1887 as muting the earlier cases).
30. In this context, although pharmaceutical companies tend to present high numbers related to the cost of drug development in general or a specific drug in particular, those figures may include research and development into new drugs or into approaches that failed.
31. See Global Health Justice Partnership, *Curbing Unfair Drug Prices: A Primer for States* at 3 (Aug. 2017).
32. Georgia General Assembly SB 200, effective July 1, 2017.
33. New York State Senate Assembly Bill A3007B, January 23, 2017.
34. See Graham Atkinson, *State Hospital Rate-Setting Revisited*, THE COMMONWEALTH FUND, October 2009, available at <https://pdfs.semanticscholar.org/275e/9c9f8190f1fd4ca66b83bf475f58a2b01333.pdf>
35. See David Frankford and Sara Rosenbaum, *Taming Health Care Spending: Could State Rate Setting Work?*, HEALTH AFFAIRS BLOG (March 20), 2017, available at <https://www.healthaffairs.org/doi/10.1377/hblog20170320.059262/full/>; David Dayen, *Single Payer, Meet All Payer: The Surprising State That is Quietly Revolutionizing Health Care*, THE INTERCEPT, July 24, 2017, available at <https://theintercept.com/2017/07/24/single-payer-meet-all-payer-the-surprising-state-that-is-quietly-revolutionizing-healthcare/>
36. See Ashok Selvam, *Hitting the reset button – More states consider return to rate-setting*, MODERN HEALTHCARE (December 5, 2011), available at
37. See *Equalizing Health Provider Rates – All Payer Rate Setting*, NATIONAL CONFERENCE OF STATE LEGISLATURES (June 2010), available at http://www.ncsl.org/portals/1/documents/health/ALL_PAYER_RATES-2010.pdf
38. See Thomas L. Greaney, *Coping With Concentration*, 36 HEALTH AFFAIRS 1564, 1571 n.52 (2017).
39. See DEPARTMENT OF HEALTH AND HUMAN SERVICES, *Medicaid Drug Pricing in State Maximum Allowable Cost Programs* (August 2013), available at <https://oig.hhs.gov/oei/reports/oei-03-11-00640.pdf>
40. See *id.*
41. See Ann Boynton and James C. Robinson, *Appropriate Use Of Reference Pricing Can Increase Value*, HEALTH AFFAIRS BLOG (July 7, 2015), available at <https://www.healthaffairs.org/doi/10.1377/hblog20150707.049155/full/>