

COMMITTEE NO. 413

IP LICENSING

Scope of Committee: All issues relating to intellectual property licensing and other contracts involving the ownership, transfer or exchange of intellectual property rights, excluding security interests which are within the scope of Special Committee 465 and franchising issues which are within the scope of Committee 207.

Subject 1. STATE PRESCRIPTION DRUG COMPULSORY LICENSING

PROPOSED RESOLUTION 413-1

RESOLVED, that the Section of Intellectual Property Law is opposed, in principle, to any state or local law that provides for compulsory licensing of any patented pharmaceutical product or process.

RESOLVED, that the Section of Intellectual Property Law reaffirms its position, in principle, to statutory provisions permitting compulsory licensing of patents and SPECIFICALLY, the section opposes enactment of the "Public Health Emergency Medicines Act" H.R. 4131, 109th Congress as introduced on October 25, 2005, and thereafter referred to the House Committee on the Judiciary and House Committee on Energy and Commerce, or similar legislation.

Past Action. (Passed 2002 AR87-R101-7) -- Section reaffirms its position, in principle, to statutory provisions permitting compulsory licensing of patents and SPECIFICALLY, the section opposes enactment of the "Affordable Prescription Drugs and Medical Inventions Act" H.R. 1708, 107th Congress as introduced on May 5, 2001, and thereafter referred to the House Committee on the Judiciary and House Committee on Energy and Commerce, or similar legislation.

Discussion. As set forth in its report below, Subcommittee A (Patent Licensing) of this Committee 413 joined Subcommittee A (Prescription Drug Compulsory Licensing) of Committee 108 to prepare a joint resolution (Nos. 413-1 and 108-1, respectively) pertaining to state compulsory licensing of pharmaceuticals for consideration by the IPL Council. A vote of Committee 413 was taken, with a quorum participating, and the resolution and related report were approved. The vote tallies are set forth following the discussion below.

State compulsory patent licensing allows a state government to grant licenses to make, use, or sell, a patented invention by the state or its designees, without the permission of the patentee. Prompted by the perceived unreasonable cost of patented pharmaceuticals, and the inability of some patent holders to manufacture sufficient amounts of potentially life-saving drug treatments, state governments have exhibited signs of resorting to the issuance of compulsory licenses for pharmaceutical compositions protected by a U.S. Patent. The compulsory licenses would effectively permit the states to force a patentee, in most cases a pharmaceutical company that patents a useful and innovative new pharmaceutical composition, into a license agreement.

Using the compulsory license, the state government would permit third parties to manufacture and sell the pharmaceutical composition in competition with the patentee in an attempt to greatly reduce prices to, for example, Medicaid patients and state employees.

The two most comprehensive proposals of recently considered compulsory licensing schemes are from West Virginia and the District of Columbia, and provide a good illustration of the typical proposals being considered and a platform to discuss the various potential constitutional issues and economic implications.¹ D.C. Councilman David Catania introduced legislation this past February entitled the “Prescription Drug Compulsory Manufacture License Act of 2005” (hereinafter D.C. Act).² The legislation as initially proposed would have granted extraordinary power to the Mayor to declare public health and safety would be served by requiring the issuance of a license for generic manufacture of a prescription drug protected by one or more patents. The legislation underwent significant editing and change and, following unanimous approval by the city council, was signed into law on October 3, 2005 by Mayor Anthony Williams as the “Prescription Drug Excessive Pricing Act of 2005”³, but without the provisions related to compulsory licensure. The law would have allowed lawsuits to be filed against drug companies by the D.C. government or an individual if the wholesale price of a patented prescription drug in the District is 30 percent higher than the price in Australia, Canada, Germany or the United Kingdom. However, the United States District Court for the District of Columbia has recently found the D.C. Act preempted by federal law and unconstitutional on its face. *Pharmaceutical Research and Manufacturers of America v. The District of Columbia, et al.*, Memorandum Opinion of December 22, 2005 at 12-18. (D.C. DC 2005). The Court additionally found that the D.C. Act, as applied, had a per se invalid extraterritorial reach and was therefore unconstitutional as a violation of the Commerce Clause. *Id.* at 26-27.

Another program is West Virginia Pharmaceutical Cost Management Council’s Compulsory Licensing proposal. Manufacturers would be required to sell their drugs “at a reasonable price” to a single wholesaler contracted by the state to purchase drugs. Alternative forms of the proposal include limiting the wholesaler to be responsible to purchase drugs for state employees and citizens covered by state Medicaid programs, and alternatively, responsibility to purchase drugs for all citizens of West Virginia. The state would define a “reasonable price” as being equivalent to or below the price paid by the Australian Pharmaceutical Benefits Scheme. If the manufacturer refuses to do so, the state would grant a license to other manufacturers to produce generic versions of that drug.

Compulsory licensing proposals generate constitutional implications as well as many derivative considerations and questions. In addition, discussion of such potential legislation breeds many related musings and inquiries including how to determine which drugs or treatments would be

¹ It is anticipated that many states will follow suit. Indeed, states such as Maine, Alabama and Vermont, have all discussed some form of compulsory license legislation.

² A copy of the bill in its original form can be found at <http://www.dccouncil.washington.dc.us/images/00001/20050211092234.pdf>.

³ A copy of the Act can be found at <http://www.dccouncil.washington.dc.us/images/00001/20050927163237.pdf>.

targeted, discrepancies in who would be allowed to receive the generic version, and economic consequences. These and related issues are discussed in detail in this report.

I. CONSTITUTIONAL ISSUES POTENTIALLY AFFECTING STATE COMPULSORY LICENSING EFFORTS

A. State Sovereignty

The Supreme Court's decision in *Atascadero State Hospital v. Scanlon*, 473 U.S. 234 (1985), is the basis for the Federal Circuit's holding that the patent laws do not contain the requisite statement of intent to abrogate state sovereign immunity from infringement suits. *See, e.g., Chew v. California*, 893 F.2d 331 (Fed. Cir. 1989). The posterity of sovereign immunity from patent infringement suits was explicitly decided in 1999 by the Supreme Court's decision *Florida Prepaid Postsecondary Education Expense Board v. College Savings Bank*, 527 U.S. 627 (1999) (holding amendment of Plant Variety Protection Remedy Clarification Act in 1992 that expressly abrogated a state's sovereign immunity for acts of patent infringement unconstitutional).

Challenges to defenses of sovereign immunity in compulsory licensing statutes could be raised based on the rationale noted by the Supreme Court in *Florida Prepaid*. Notably, the Supreme Court indicated that a state's infringement of a patent violates the Constitution only where the State provides no remedy, or only inadequate remedies, to injured patent owners for its infringement of their patent under a deprivation of property without due process theory. *Id.* at 643. Of particular importance in reaching this result was the Court's acknowledgement that "[t]estimony before the House Subcommittee acknowledged that States are willing and able to respect patent rights, and the Senate Report contains no evidence that unremedied patent infringement by States had become a problem of national import." *Id.* at 628. The facts underlying this rationale may change if states start passing drug compulsory licensing statutes. Further, compulsory licensing statutes without adequate remedy could be argued to be disrespectful of federal patent rights and lead to a significant amount of unremedied patent infringement of a key component of the national economy, thus leading to abrogation of this defense for states under Section 5 of the 14th Amendment. *See, e.g., Fitzpatrick v. Bizer*, 427 U.S. 445 (1976); *City of Boerne v. Flores*, 521 U.S. 507 (1997). Calculating adequate remedies for the compelled licenses will almost certainly play a crucial role in determining the constitutionality of these statutes.

B. Supremacy Clause / Preemption

Federal preemption is based on the Supremacy Clause, which states:

This Constitution, and the laws of the United States which shall be made in Pursuance thereof; and all Treaties made, or which shall be made, under the authority of the United States, shall be Supreme Law of the land; and the Judges in every state shall be bound thereby, any thing in the Constitution or Laws of any state to the contrary notwithstanding.

Although several different types of federal preemption exist, there are three basic forms. *G. S. Rasmussen & Assocs., Inc. v. Kalitta Flying Serv., Inc.*, 958 F.2d 896, 903 (9th Cir. 1992). First, Congress may expressly preempt state law with preemptive text (express preemption). *Cybernetic Servs., Inc. v. Matsco, Inc.*, 252 F.3d 1039, 1045 (9th Cir. 2001). Second, a scheme of federal regulation may be sufficiently comprehensive to make reasonable the inference that Congress intended to preempt an entire field of state law (hereinafter “field preemption”). *Id.* Or third, state law may be preempted when compliance with both federal and state law is impossible (hereinafter “conflict preemption”). *Id.* Significantly, common to all forms of federal preemption is whether the operation of state law “stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.” *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 479 (1974).

Since the Patent Act of 1952, including all subsequent amendments thereto (e.g., Patent Term Restoration Act of 1984), does not contain preemptive text, express preemption is inapplicable. With regards to field and conflict preemption, the U.S. Supreme Court has adopted a “pragmatic” approach to deciding whether the Patent Act preempts a particular state law. *See Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 156 (1989). This pragmatic approach is simply a balancing test between the purpose and objective of the Patent Act and state regulation of intellectual property. *See e.g., Kewanee*, 416 U.S. at 479 (quoting *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941)) (stating “state regulation of intellectual property must yield to the extent that it clashes with the balance struck by Congress” in the Patent Act); *Bonito Boats*, 489 U.S. at 152. *See also Rasmussen*, 958 F.2d at 904 (the 9th Circuit Court of Appeals has held that because Congress balanced innovation incentives against free competition in drafting the Patent Act, state laws upsetting that balance are preempted); *Sears, Roebuck & Co. v. Stiffel Co.*, 376 U.S. 225 (1964); *Compco Corp. v. Day-Brite Lighting, Inc.*, 376 U.S. 234 (1964). Since a balancing test must be performed, it is clear that only a portion of the patent law field has been preempted, rather than the field in its entirety. *Chicago and N. W. Transp. Co. v. Kalo Brick & Tile Co.*, 450 U.S. 311, 317 (1981). Accordingly, the courts have generally found that state law is not preempted merely because it relates to patents or patentable inventions. *See Aronson v. Quick Point Pencil Co.*, 440 U.S. 257, 262 (1979) (concluding that commercial agreements are traditionally the domain of state law, therefore state law is not displaced merely because the contract relates to intellectual property). On the other hand, the 9th Circuit has gone so far as to find that “the fact that patent law *could* reach it [the area covered by the state law] preempts state-law protection.” *Rasmussen*, 958 F.2d at 904 (emphasis included).

In *Kewanee*, the Supreme Court turned to the Constitution for guidance on determining whether a state statute stood as an obstacle to the accomplishment and execution of the purpose and objective of the Patent Act. 416 U.S. at 480. Article I, Section 8, Clause 8 of the Constitution empowers Congress to legislate in the area of intellectual property to “promote the Progress of Science and useful Arts.” The Court in *Kewanee* concluded that “[t]he patent laws promote this progress by offering a right of exclusion for a limited period as an incentive to inventors to risk the often enormous costs in terms of time, research, and development.” *Id.* The Supreme Court has also recognized that the patent laws reflect Congress’s “carefully crafted bargain” among competing interests. *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 63 (1998); *Bonito Boats*, 489 U.S. at 150-151. Congress expects that the twenty years of exclusive use granted to

the patentee for his disclosure will stimulate ideas and the eventual development of further significant advances in the art; in other words, it creates the incentive to invent, even in the face of certain risks. *Kewanee*, 416 U.S. at 481. In turn, it is believed that the productivity and innovation fostered by the system will have a positive effect on society through the introduction of new products and processes of manufacture into the economy, translating into increased employment and better lives for U.S. citizens. *Kewanee*, 416 U.S. at 481. Therefore, “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.” See *Kendall*, 62 U.S. at 327-328; *Sears, Roebuck & Co.*, 376 U.S. 225 (the right to exclusivity granted by the Patent Act is subject to the “rights and welfare of the community [which] must be fairly dealt with and effectively guarded.”).

It seems likely that any disruption to the careful balance embodied in the Patent Act between a grant of exclusivity on one hand, and public benefit on the other, would be preempted. See e.g. *Pharmaceutical Research and Manufacturers of America v. The District of Columbia, et al.*, Memorandum Opinion of December 22, 2005 at 12-18. (D.C. DC 2005) (“using the litigation process to determine on a drug to drug basis the application of a given drug’s pricing vis a vis that in a foreign country directly interferes with, and second guesses, the balance set by Congress in the current system of patents and market exclusivity for pharmaceutical products.”). The “benefit to the public” from the introduction of new products and processes of manufacture has already been balanced on a term of years right to exclude. Restrictions on the right to exclude after generation of the innovation spurred by the incentive of exclusivity would upset the balance envisioned by Congress. *Id.* This is especially true if a state compulsory licensing scheme for pharmaceutical patents does not provide just compensation, or offers compensation at less than the minimum afforded by current governmental limitations of a patentee’s exclusive right. See e.g., 28 U.S.C. §1498 wherein the federal government must pay “reasonable and just compensation” to a patentee when taking a compulsory license; *Standard Mfg. Co. v. United States*, 42 Fed. Cl. 748 (1999) (reasonable compensation is the reasonable royalty afforded by the patent statute plus damages for delay in paying royalty); *Textronic Inc. v. United States*, 213 Ct. Cl. 257 (1977) (lost profits only available on the strictest proof, that the patentee would have actually earned and retained sums on sales to the federal government).

Opponents of patented drug compulsory licensing schemes may argue that the risk of upsetting the balance is even greater due to the nature of pharmaceutical research and the tenuous task of creating safe and effective drugs (including, but not limited to, conducting years of testing to receive FDA approval and having to finance the myriad of failed attempts on the commercial success of one product). See e.g. *Pharmaceutical Research and Manufacturers of America v. The District of Columbia, et al.*, Memorandum Opinion of December 22, 2005 at 15 (D.C. DC 2005) (“Congress’ [sic] regulation of our nation’s pharmaceutical industry is grounded in large part in a complex balance of economic forces and regulatory exclusivity designed to encourage and reward the innovation, research, and development of new drugs.”). These costs should not be ignored by the states when determining “reasonable and just compensation,” and any attempt by states to arbitrarily remove any compensation, or to assign some across-the-board amount or percentage, should be shunned in favor of hearings to fairly and adequately address compensation of at least a commercial reasonable royalty for each inherently unique discovery.

Opponents of the compulsory licensing schemes may further argue that the constitutional balance established by Congress and incorporated in the Patent Act, along with the relevant case law, requires at minimum such hearings to recreate the balance between the “benefit to the public” and the right to exclusivity. Otherwise, such compulsory licensing schemes may stand as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.

Furthermore, the preemption issue necessarily gives rise to the question of whether a state granted license would provide any benefit at all to the “licensee”. A manufacturer granted a license by the state of West Virginia for example, could still face patent infringement litigation in the federal courts of the 4th Circuit (the circuit governing West Virginia) applying federal law. The grant of a license by West Virginia to produce and sell an otherwise infringing product within the borders of the state would have no effect upon a federal court’s determinations regarding infringement, regardless of where the activity took place and regardless of the fact that West Virginia granted the license.

C. Due Process

1. Substantive

Any compulsory licensing statute enacted by a state would likely be found to be an economic regulation for due process principles and therefore likely upheld by the courts (the U.S. Supreme Court has not struck down a state economic regulation for substantive due process concerns since 1937)⁴. For economic regulations to survive due process challenges, they “shall not be unreasonable, arbitrary or capricious, and that the means selected shall have a real and substantial relation to the objective sought to be obtained.” *Nebbia v. New York*, 291 U.S. 502 (1934). Specifically, a state is free “to adopt whatever economic policy may reasonably be deemed to promote public welfare, and to enforce that policy by legislation adapted to its purpose.” *Id.* Further, a presumption of constitutionality would be applied to economic regulations subject to a due process attack. *See, e.g., United States v. Carolene Prods. Co.*, 304 U.S. 144 (1938). The courts, in later years, went even further in finding that one who attacks economic regulations under due process not only has the burden of rebutting the reasons given by the legislature, but also reasons the legislature “might have considered.” *See, e.g., Williamson v. Lee Optical of Okla., Inc.*, 348 U.S. 483 (1955). The courts’ continued lowering of scrutiny of economic regulations has continued since the 1950s when the Supreme Court found that courts should “refuse to sit as a ‘superlegislature’ to weigh the wisdom of legislation” and therefore have “abandoned the use of the ‘vague contours’ of the Due Process Clause to nullify laws which a majority of the Court believed to be economically unwise.” *Ferguson v. Skrupa*, 372 U.S. 726 (1963). This was reiterated in *Duke Power* where the Supreme Court held that if the objective in an economic regulation falls within the state’s legitimate ‘police power,’ e.g., the health, safety, or general welfare of its populace, all substantive due process requires is that there is a minimal rational relation between the ends and the means. *Duke Power Co. v. Carolina Envtl. Study Group Inc.*, 438 U.S. 59 (1978).

⁴ Almost all statutes since the 1930s that have not dealt with restrictions to a “fundamental right” such as life, liberty or privacy have been found to be an economic regulation for substantive due process analysis.

2. Procedural

Due to the treatment of intellectual property as a personal property, any compulsory licensing statute enacted by a state would likely be found to affect a 14th Amendment “property interest.”⁵ In order to be subject to procedural due process protection, a property interest must be “already acquired.” See e.g., *Board of Regents v. Roth*, 408 U.S. 564 (1972). This requirement would preclude all but patent holders from challenging the compulsory licensing statute on procedural due process grounds. *Id.* After a “property interest” is affected, the only question remaining for procedural due process concerns is what process is due in order to impair that property interest. Three factors are evaluated in determining to what extent the process must go: (1) “the private interest that will be affected by the official action”; (2) “the risk of erroneous deprivation of such interest through the procedures used, and the probable value, if any, of additional or substitute safeguards”; and (3) the government’s interest, including the function involved and the fiscal and administrative burdens that the additional or substitute procedural requirement would entail.” *Mathews v. Eldridge*, 424 U.S. 319, 335 (1976). The procedures mandated by this balancing can range from a full evidentiary hearing (see, e.g., *Goldberg v. Kelly*, 397 U.S. 254 (1970), for taking welfare benefits; *BMW of N. Am. v. Gore*, 517 U.S. 559 (1996) for grossly excessive awards of punitive damages) to a simple hearing and informal ruling.

Applying the *Mathews* test outlined above, it is likely that the balancing test would require a full evidentiary hearing with the right to call witnesses, right for cross-examination, and judicial review for compulsory licensing statutes that set royalty rates for pharmaceutical patents. Under *Mathews*, the more valuable the interest the more procedure is required. The interest affected in a pharmaceutical compulsory licensing scheme (e.g., revenue due from reasonable royalty or other calculation) is significant and may well exceed any strictly monetary interest evaluated by the courts under a procedural due process analysis⁶. In light of the significant interest at stake and the complex nature of determining just compensation⁷, anything short of a detailed evidentiary hearing as outlined above would fail the *Mathews* requirements.

D. Commerce Clause

“Congress shall have the power . . . to regulate Commerce with foreign Nations, and among the several States, and with the Indian Tribes.”

U.S. CONST. art. I, § 8, cl. 3. However, the Constitution does not articulate the boundaries of this commerce power in the face of Congressional silence. The compatibility of state or local laws

⁵ A more detailed discussion of the private property status of patents may be found in the Eminent Domain Section, *supra*.

⁶ Revenues from sales of patented pharmaceutical compositions can annually reach into the billions of dollars.

⁷ The complexities of determining just compensation include all the complexities of determining at least a reasonable royalty as a damages award for patent infringement. See e.g., 35 U.S.C. §284

with the commerce clause in the face of Congressional silence is evaluated under “dormant commerce clause” principles.⁸

Traditionally, two different types of state or local laws have been found to affect commerce: (1) state laws that discriminate against out-of-state competition and (2) non-discriminatory state laws that impose incidental burdens on interstate commerce. State regulations which affect interstate commerce (such as compulsory licensing statutes) must: (1) have a legitimate state purpose⁹; (2) be rationally related to that purpose; and (3) the burden imposed by the regulation on interstate commerce, along with any discriminatory effect, must be outweighed by state’s interest in enforcing the regulation. See e.g. *Pike v. Bruce Church Inc.*, 397 U.S. 137 (1970). Equally important, evaluation of these factors favors state governments in two ways: (1) the party challenging the statute has the burden of proof; and (2), to overturn, the burden on interstate commerce must clearly be excessive. *Id.* at 142.

Proponents of non-discriminatory compulsory licensing statutes could cite to the state’s interest in providing potentially life-saving pharmaceuticals to its less-wealthy constituency, which might be significantly advanced by producing cheaper drugs under compulsory licenses, while the incidental effect on interstate commerce is justified. See e.g., *Minnesota v. Clover Leaf Creamery Co.*, 449 U.S. 456 (1981) (burden on interstate commerce justified when compared to state’s interest in protecting its environment). If some compensation (even if not adequate under a due process analysis) is provided for the compulsory license, proponents would have additional rationale further tilting the scale in the state’s favor.

Opponents of compulsory licensing schemes, especially in states where there are few if any pharmaceutical production facilities, could point to the fact that although facially neutral, a compulsory licensing statute is effectively discriminatory. A showing of a discriminatory effect would be a significant reason to find a compulsory licensing statute unconstitutional. See, e.g., *Kassel v. Consol. Freight Corp.*, 450 U.S. 662 (1981); *Hunt v. Wash. State Apple Adver. Comm’n*, 432 U.S. 333 (1977) (The Court held that a law acted discriminatorily despite neutral language on its face, because the statute removed a trade advantage from out-of-state market participants). Although not directly addressing the confronting the compulsory licensing scheme section in the D.C. Act, the court in *Pharmaceutical Research and Manufacturers of America*, Memorandum Opinion of December 22, 2005 at 18-27 (D.C. DC 2005), found that a provision in the D.C. Act had a per se invalid extraterritorial reach because, among other things, drug companies manufacture wholly outside of D.C., they are not headquartered in D.C., they do not

⁸NOWACK, *supra* note 2, § 8.1, at 319. The dormant commerce clause embodies the concept that mere grant of a commerce power to Congress in Article I, §8 by implication places limits upon states and local governments regulation of commerce.

⁹Discriminatory regulations, e.g., tariffs or other trade barriers are not legitimate purposes and almost always fail for this reason unless no reasonable alternatives are available. See e.g., *Maine v. Taylor*, 476 U.S. 1138 (1986); *C&A Carbone, Inc. v. Town of Clarkston*, 511 U.S. 383 (1994). Further, state laws that seek to regulate out-of-state commerce are per se unconstitutional. See e.g., *Pharmaceutical Research and Manufacturers of America*, Memorandum Opinion of December 22, 2005 at 18-27 (D.C. DC 2005) (citing *Brown-Forman Distillers Corp. v. New York State Liquor Author.*, 476 U.S. 573 (1986); *Healy v. Beer Inst.*, 491 U.S. 324 (1989)).

operate warehouses in D.C., and the overwhelming bulk of drug sales occur outside of D.C. However, cutting against this argument, the Supreme Court in *Pharm. Research and Mfrs. of Am. v. Walsh*, 538 U.S. 644 (2003), decided that opponents seeking an injunction to a state program forcing drug companies into a rebate program did not carry their burden of showing a probability of success on a Commerce Clause challenge. The opponents argued that the statute constituted impermissible extraterritorial regulation and discriminated against interstate commerce in order to boost in-state sales. But the Court held that the opponents did not meet their burden, because, among other things, the statute did not force out-of-state manufacturers to sell at certain prices, it was not tying the price of in-state products to out-of-state prices, and it was not imposing a disparate burden on out-of-state companies because the obligations could not be avoided simply by opening a production facility in the state.¹⁰

Opponents of compulsory licensing statutes could also raise concerns that pharmaceutical pricing is an aspect of commerce that requires uniform national treatment. Arguably, this can be provided only by Congress as residents from all states will use all the tools of commerce to achieve the cheapest rational prices for pharmaceuticals, thus creating a race to the bottom in state compulsory licensing statutes. Indeed, the District of D.C. in *Pharmaceutical Research and Manufacturers of America v. The District of Columbia, et al.*, specifically considered this issue, stating,

Moreover, as recognized by the Supreme Court in *Healy*, ‘the practical effect of the [challenged] statute must be evaluated not only by considering the consequences of the statute itself, but also by considering how the challenged statute may interact with the legitimate regulatory regimes of other States and what effect would arise if not one, but many or every, State adopted similar legislation. Although no other state has adopted a statute like the D.C. Act to date, it takes little imagination to envision the harm to interstate commerce that could be caused by the domino effect of similar legislation being adopted in many, or every, state. For example, similar legislation throughout the country would undoubtedly result in an artificial race between legislatures to set the lowest [price]. Such races to the bottom of the marketplace can be as dangerous to the interstate market as any other type of market failure, such as monopoly or price-tying measures.’”

Memorandum Opinion of December 22, 2005 at 18-27 (D.C. DC 2005) (citations omitted). Additionally, opponents of such compulsory licensing statutes could argue that these statutes are not the least intrusive manner to achieve the state’s purpose, and that other manners of regulation, *e.g.* price controls, should be adequately explored before undermining federally granted patent rights, and forcing companies from other states into licensing agreements, as well

¹⁰ The court in *Pharmaceutical Research and Manufacturers of America v. The District of Columbia, et al.*, Memorandum Opinion of December 22, 2005 at n.15 (D.C. DC 2005), specifically distinguished the Supreme Court’s decision in *Pharm. Research and Mfrs. of Am. v. Walsh*, based solely on the regulatory effect the D.C. Act will have on the price of out-of-state transactions, although the same rationale might not apply when confronting the compulsory licensing aspects of the D.C. Act.

as enticing out-of-state residents into the state in order to buy their pharmaceuticals. *See, e.g., Dean Milk Co. v. City of Madison*, 340 U.S. 349 (1951). As noted in commentary addressing West Virginia’s efforts to enact compulsory licensing legislation, “West Virginia can no more ‘license’ others to make a patented drug than it can issue or invalidate passports, or regulate commerce with Indian tribes.”¹¹

E. State Police Power

Since a patent does not confer the affirmative right to practice the subject matter claimed or disclosed in the patent; proponents of state compulsory licensing laws that are enacted to protect the public interest may argue that such laws are constitutional under the state’s police power. Proponents could point to laws that have been upheld as constitutional, that would prohibit or restrict the practice of an embodiment. These valid regulatory laws simply constitute a state’s lawful exercise of its police power.

However, opponents of state compulsory licensing statutes may point out that this is not the case for a state action undermining federally granted patent rights, such as the right to exclude others from making, using or selling the patented subject matter, *i.e.* a pharmaceutical composition, as opposed to simply regulating the practice of embodiments of the patent. *See e.g., Patterson v. Kentucky*, 97 U.S. (7 Otto) 501, 24 L. Ed. 1115 (1878).¹² Patent rights (*i.e.*, the right to exclude) are immune from abrogation by any state legislation allegedly ratified under the state police power, notwithstanding the state’s ability to regulate an embodiment of that patent. (*See also Webber v. Virginia*, 103 U.S. (13 Otto) 344, 348 (1880)(“The patent for a dynamite powder does not prevent the State from prescribing the conditions of its manufacture, storage and sale, so as to protect the community from the danger of explosion. A patent for the manufacture and sale of a deadly poison does not lessen the right of the State to control its handling and use. The legislation respecting the articles which the State may adopt after the patents have expired, it may equally adopt during their continuance. *It is only the right to the invention or discovery--the incorporeal right--which the State cannot interfere with.* Congress never intended that the patent laws should displace the police powers of the States, meaning by that term those powers by which the health, good order, peace and general welfare of the community are promoted. Whatever rights are secured to inventors must be enjoyed in subordination to this general authority of the State over all property within its limits.”); *Aronson v. Quick Point Pencil Co.*, 440 U.S. 257, 262 (1979) (“State law is not displaced merely because the contract relates to intellectual property which may or may not be patentable; the states are free to regulate the use of such intellectual property in any manner not inconsistent with federal law.” – sales contract requiring one party to pay inventor royalty held enforceable even though patent was not obtained); *United States v. Masonite Corp.*, 316 U.S. 265, 279, 62 S. Ct. 1070, 1078, 86 L. Ed. 1461, 53 USPQ 396 (1942) (“Since patents are privileges restrictive of

¹¹ See *Legal Issues Raised by Rx Council’s Compulsory Licensing Proposal*, Covington & Burling, 2005, at <http://cptech.org/ip/health/cl/covington-burling-wvacllaw.pdf>.

¹² Compare *Patterson*, 97 U.S. at 505 (“the right conferred upon the patentee and his assigns to use and vend the corporeal thing or article, brought into existence by the application of the patented discovery, must be exercised in subordination to the police regulations which the State established by the statute[.]”) to *Patterson*, 97 U.S. at 506 (“...[The enjoyment of the right in the discovery] may be secured and protected by national authority against *all* interference...”)(emphasis added).

a free economy, the rights which Congress has attached to them must be strictly construed so as not to derogate from the general law beyond the necessary requirements of the patent statute.”)

F. Takings Clause: Eminent Domain

States and the Federal government have the right to take private property for public use, provided that just compensation is paid. *See e.g.*, 5th and 14th Amendments (“private property [shall not] be taken for public use, without just compensation”). First, Congress itself believes that patents are property that can be taken:

[T]he bill is justified as an acceptable method of enforcing the provisions of the fourteenth amendment. The Court in *Lemelson v. Ampex Corp.*, recognized that a patent is a form of property, holding that a right to compensation exists for patent infringement. Additionally, because courts have continually recognized patent rights as property, the fourteenth amendment prohibits a State from depriving a person of property without due process of law.

S. Rep., at 8 (footnotes omitted) on Patent Reform Act of 1992.

Further in *Florida Prepaid*, the Supreme Court found:

[i]n procedural due process claims, the deprivation by state action of a constitutionally protected interest . . . is not in itself unconstitutional; what is unconstitutional is the deprivation of such an interest without due process of law." *Zinermon v. Burch*, 494 U.S. 113, 125 (1990) (emphasis deleted). Thus, under the plain terms of the Clause and the clear import of our precedent, a State's infringement of a patent, though interfering with a patent owner's right to exclude others, does not by itself violate the Constitution. Instead, only where the State provides no remedy, or only inadequate remedies, to injured patent owners for its infringement of their patent could a deprivation of property without due process result. *See Parratt v. Taylor*, 451 U.S. 527, 539-531 (1981); *Hudson v. Palmer*, 468 U.S. 517, 532-533 (1984); *id.* at 539 (O'CONNOR, J., concurring) (" [I]n challenging a property deprivation, the claimant must either avail himself of the remedies guaranteed by state law or prove that the available remedies are inadequate When adequate remedies are provided and followed, no . . . deprivation of property without due process can result").

Clearly, with respect to patents, the Federal Circuit has explicitly stated that they are “property” to the federal government.

“the [federal] government can simply ‘take’ the invention where warranted by public interest concerns and provide ‘adequate compensation’ to the patent holder.

28 U.S.C. § 1498 (1988).” *King Instruments Corp. v. Perego*, 65 F.3d 941, 959 (Fed. Cir. 1995). Furthermore, both U.S. state and federal governments have already extended the definition of “property” to intangible property interests. See e.g., *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 1003-1004 (1984) (trade secrets); *Lynch v. United States*, 292 U.S. 571, 579 (1934) (business goodwill, labor, trade routes, contracts); *City of Oakland v. Oakland Raiders*, 32 C.3d 60 (Cal. Sup. Ct. 1982)(franchises, and even football teams for the public use of “public health, recreation and enjoyment”).

Generally, a taking requires a public use that does not leave an economically viable use of the property to the owner; less than that is a regulation that does not require the government to provide “just compensation.” See e.g., *Agins v. City of Tiburon*, 447 U.S. 255 (1980) (application of taking v. regulation in land use case); *Pa. Coal Co. v. Mahon*, 260 U.S. 393 (1922) (the greater reduction in value of the property the more likely it is a taking).

Proponents of a compulsory licensing statute are not likely to dispute the taking v. regulation issue given the implication of 28 U.S. §1498, but could point to the Supreme Court’s decision in *New London*, finding that the requisite “public use” necessary to undertake a state government taking has been extended to a “public purpose,” a very broad range conceivably extending to public health issues like AIDS or any other disease for that matter. *Kelo v. City of New London, Conn.*, 125 S.Ct. 265 (2005)(finding that economic redevelopment was a sufficient public purpose); See also, *Haw. Hous. Auth. v. Midkiff*, 467 U.S. 229 (1984)(“public use” is “coterminous with the scope of a sovereign’s police power”). Therefore, simply all that is required for constitutionality of such statutes is “just compensation.”

However, what constitutes “just compensation” in this context is another complex question of fact and law, and has not been adequately addressed by the states. For example, West Virginia’s proposal never contemplates compensation, and any proposal that does including D.C.’s, fails to consider the complexity of defining “just compensation” with regards to patent rights and pharmaceuticals. The obvious question is how just compensation would be calculated for a patent covering a pharmaceutical composition. Some scholars argue you must add up all the research and development costs which could include the clinical phase trials, fees for procuring the patent (legal fees, USPTO fees, and the cost of gaining FDA approval), marketing, manufacturing and distribution set-up costs if applicable and all profits. Conservative estimates put the cost of bringing a drug from the laboratory bench to the pharmacy shelves at around \$500 million to \$800 million – and then on top of that add profits lost. That is a cost that the patent holder would have to be reimbursed. As anyone versed in the field of pharmaceuticals can well attest, many drug products are covered by multiple patents, so conceivably, the state would have to reimburse per patent.

Opponents of a compulsory licensing statute are also likely to point to the distinction between the types of property being taken. See e.g., *Mayor of Baltimore v. Baltimore Football Club, Inc.*, 624 F. Supp. 278, 284 (D. Md. 1985) (a government cannot take property that exists outside of its territorial limits). The right to exclude is a federally granted right in property that spans the entire nation, it is not confined to one state’s borders; thus, it is arguably outside the territorial limits of the state. Further, opponents could distinguish 28 U.S.C. §1498 as a more restrictive regulation than is necessary since “negligent acts” do not deprive that person of

property under the Due Process Clause and patent infringement does not require an intent element. *See, e.g., Daniels v. Williams*, 474 U.S. 327, 328 (1986) and would at least argue for explicit statutory language that a compulsory licensing program satisfies the intent element necessary to find a Due Process violation.

II. OTHER ISSUES AFFECTING STATE COMPULSORY LICENSING EFFORTS

A. Implications of the Hatch-Waxman Act on State Compulsory Licensing Efforts

Compulsory licensing schemes such as contained in these proposals also fail to consider the implications inherent in bringing any drug product onto the market in the United States. In order to sell a drug product in the U.S., that drug must first be approved by the Food and Drug Administration (FDA) and certified to be safe and effective for its stated use. In 1984, Congress passed sweeping legislation and amendments to the Federal Food, Drug & Cosmetic Act, the law governing the process of gaining FDA approval, known as the Hatch-Waxman Amendments. These amendments created a specific procedure for filing an Abbreviated New Drug Application (ANDA) for generic alternatives to already approved drugs. This process greatly reduces the multi-year regulatory approval time and significant costs to a generic drug applicant to gain FDA approval. One of the requirements in the legislation is that an ANDA must contain a certification as to each and every patent listed in the FDA's Orange Book claiming to cover the already approved drug the ANDA is referencing. The type of certification required is referred to by paragraph. The paragraph IV certification is typically most problematic and implicated by compulsory licensing proposals. This paragraph IV certification asserts that the generic version will not infringe the patent, or that the patent is invalid or unenforceable. What kind of certification would a generic manufacturer granted a license by a state, not by the patent holder, make under a federal law? Could a generic reasonably assert that they do not infringe the patent, when arguably the license they were granted was likely done so under an unconstitutional law and the grantor never had the authority to grant the license in the first place? A generic applicant might not be able to comply with the requirements of the federal law regarding certification procedures, and thus its application would be incomplete and the drug not approved.

Under the statutory scheme, whenever an ANDA filer is the first to include a paragraph IV certification against a patent, the mere filing of which is statutorily an act of infringement, that ANDA filer gets sued by the patent holder, a circumstance that procedurally results in a freezing of the consideration of the ANDA for two and a half years. What benefit does that grant to a state's consumers if the drug will not even get approved for a minimum of thirty months at least? And regardless of whether the approval process is stayed, the reality is that the patent holder most likely will sue the ANDA applicant in any event. Would the state have to compensate the ANDA filer for the cost of the litigation, or indemnify them against any lawsuits? That is an additional cost that must be borne by the state's taxpayers.

Also, consideration must be paid to already pending ANDA applications and/or licensees. Imagine an Abbreviated New Drug Application is pending before the FDA. The generic company spent significant time and money preparing its generic formulation, running its bioequivalence trials, paying its attorneys, its application is pending, it even has the 180-day exclusivity granted to the first paragraph IV ANDA filer. It may have built the company on this

product, received investment based on this product, or tied up significantly all of the company's assets and capital in this product. West Virginia unilaterally decides to grant a license to produce a generic of that drug product to another manufacturer, effectively cutting the first generic out of the profitability of what they are doing, or placing the entire company at risk. And in any event, West Virginia's grant of a license does not automatically allow the manufacturer to start making the generic and immediately selling it – they still have to get FDA approval. If there is a paragraph IV ANDA filer before them whose approval is currently stayed because of pending litigation, but once they finally commercialize will receive the benefit that the FDA will not approve any other ANDAs for six months, it could still take years for the state's manufacturer to provide a generic alternative. Or, what if a brand name has already granted a license to another manufacturer, but it is not the one that the state has a contract with. Under its own law, for example, West Virginia MUST grant a license to its single appointed wholesaler. The state has just undermined and interfered with the license, and its value, that the other company had. Should the state have to compensate this company too and thus simply add more to the tax bill.

Moreover, Congress, by and through the Hatch-Waxman Act, has already specifically addressed the states' concerns over the high-price of innovative pharmaceuticals. This alone may be enough of a reason to preclude the states from legislating the same issue in an inconsistent manner.

B. Economic Implications Affecting State Compulsory Licensing Efforts

Questions about the constitutionality of these proposed laws and the potential conflicts they could create with other federal laws is only one implication. There are other questions and consequences that must be considered as well.

The most obvious is the financial implications already alluded to thus far. The only people paying the 'inflated' prices for the patent-protected drugs are those patients taking the medication. Programs like this would have to raise significant amounts of money, obviously in the form of taxes. What savings does this pass along to consumers? Instead of paying more money for the pill, they pay it in their tax bill, and many citizens will be paying a large increase in their tax bill for drugs they do not have, and never will, take. Furthermore, we have already considered some factors affecting "just compensation," but there is further potential escalation of the cost of compensation the state would have to pay. For instance, would compensation extend to others affected by compulsory licensing, such as the already pending ANDA applicant, or other pre-existing licensees, or give rise to another cause of action against the state? Consider a scenario where a company that already has a license and is manufacturing a generic, or the company with the pending ANDA application is a company with headquarters or research, manufacturing and/or distribution facilities in their own state. Because of the loss of the value of the license, a license the company arguably would still be obligated to pay for and perform under due to contract law, they have to lay off workers, increasing unemployment in that state. Not only will the state have to compensate the patent holder per patent as previously discussed, but it will have to compensate their licensee for defending against infringement litigation. The state may have to compensate others for taking their rights, including pre-existing licensees. Perhaps it will have to face suits and/or compensate other entities who were harmed by a compulsory license granted to another manufacturer, and the mere act of doing so could conceivably destroy

companies, hurt the state's local economy, increase unemployment, give rise to multiple causes of actions and other possible consequences. At this point, the compulsory license program would appear to cost all consumers, even those not benefiting from the availability of a generic drug because they do not use that particular medication, more than a high-priced pharmaceutical.

C. What Drugs Should Be Compulsory Licensed and Why?

Another obvious question is which drugs will be subjected to a compulsory license. Under plans like the District of Columbia's, all drugs would be if they cost more in the U.S. than they do in Australia. In other proposed schemes, the drugs targeted are those for life-threatening conditions. How would they define what is a life-threatening condition? How life-threatening does the condition have to be? Would death have to be imminent within two months, six months, or a year? In the District of Columbia's plan, clearly it is not just life saving medications but any drugs, which would include "quality of life" drugs - drugs such as Viagra (for sexual impotence), Accutane (for acne), Wellbutrin (for depression). If proposed schemes create classifications and distinguish somehow between life-threatening and lifestyle conditions, what about drugs having multiple indications? If a proposal limits implication to drugs that treat true disease, or are preventative to serious disease, but not lifestyle drugs, it creates a quandary regarding drugs with more than one indication. Consider Wellbutrin as an example. It has been linked to and approved for smoking cessation, arguably a preventative, and even life-saving, indication. But it is also prescribed for depression - arguably a lifestyle indication. Does this get covered or not? How do you decide? And if the law differentiates between prescriptions written for that drug that are only for preventative or life-saving reasons, might that encourage physicians to write prescriptions for a false use, or patients to lie to doctors to get them to tailor prescriptions for treatment purposes that would be subject to substitution by the generic?

All Washingtonians will have to pay taxes to compensate the brand name company for the taking of their rights granted by their patents. Should taxpayers be forced to pay for controversial medications, which may implicate their religious or moral beliefs? Health care, pharmaceuticals, and preventative medicine even can be controversial. Some people do not believe in taking extreme measures to save or improve life; some people do not even believe in taking any measures. What about medications related to pregnancy, such as birth control, or the so-called "abortion pill" RU486, or the morning-after pill? Conceivably, those types of medications could fall under these programs, and citizens of that state would actually be paying to subsidize medications and/or treatments they themselves are politically opposed to, or find contrary to their moral and religious beliefs.

Which leads to another consideration. Contrary to popular myth, health care treatment in this country does not only consist of medication. Why stop at pharmaceuticals? What about medical devices and supplies? Would asthma inhalers qualify? What about wrist splints for carpal tunnel syndrome? What about surgical equipment? What about drugs for which there is no generic alternative close to being developed?

Consider the inequity that is inherent in certain proposals, such as West Virginia's alternative proposal limiting the availability of a generic drug manufactured under a compulsory license to only those people receiving drugs under Medicaid, or who are state employees. All

citizens would have to pay increased taxes to pay for these programs, but only certain citizens would be allowed to reap the benefits. One can easily imagine a situation where two people are standing in line at the pharmacy, getting the same drug for the same condition. One is an MTA bus driver and thus a state employee, and the other is a privately employed citizen, say a carpenter not covered under Medicaid. Only the state employee would be allowed to have his prescription filled with the less expensive generic that was manufactured by the state's licensed company, but the other would not be allowed to receive the generic and would have to pay the higher price for the brand name. Might people drop private insurance coverage and seek coverage under a state's Medicaid program so that they could qualify to receive the more affordable drug, thus increasing the cost of the Medicaid program as well for the state with increased enrollment? The implications and variety of scenarios resulting from such programs could go on and on.

D. Negative Implications on the Innovative Pharmaceutical Industry

Finally, what implications would this have on the pharmaceutical industry as a whole? There is some validity to the argument that researching and developing new drugs is incredibly expensive, and to get the money to undertake these attempts, drug companies need to recoup those costs through profits. If they cannot make enough return on their pre-existing medications due to compulsory licensure, they may not have enough to funnel back into research and development of sorely needed new treatments and pharmaceuticals. If certain state programs such as D.C.'s tie the licenses to the costs of the medications in foreign countries, it could potentially incentivize drug companies to pull necessary drugs from those countries to avoid triggering the compulsory licensing in a state here in the United States, a much more lucrative market, a move that would still cost the companies millions or billions of dollars from their R&D budgets.

E. TRIPS

The TRIPs agreement (Agreement on Trade-Related Aspects of Intellectual Property Rights) was introduced under the General Agreement of Tariffs and Trade (GATT) and embodies the work of both developing and developed nations (including the United States) in the WTO (World Trade Organization) to agree on an international minimum standard for the protection of intellectual property rights. It also contains a provision that allows for compulsory licensing subject to certain requirements. During the negotiations leading to TRIPs, the U.S. and other developed nations vehemently opposed a compulsory licensing provision, or at the very least, worked hard to limit such provisions.

Proponents of compulsory licensing statutes could point to Article 31 of TRIPs, that permits governments of member nations to compel licensing of pharmaceuticals, subject to certain restrictions. Based on the U.S. participation in TRIPs, state licensing of pharmaceuticals could then be argued to be consistent with that policy and therefore not preempted. Under TRIPs, the WTO member country seeking the license must pay the patentee "adequate remuneration" and show unsuccessful negotiation for a mutually agreeable license. However, the requirement to negotiate is waived if there is "a national emergency" or a "circumstance []of extreme urgency," or if the invention is used for "public noncommercial use." The use must be

non-exclusive and non-assignable, and unless the patentee has engaged in some monopolistic behavior¹³, the license must be used to satisfy only a domestic need¹⁴, and the license will be terminated “if and when the circumstances which led to it cease to exist and are unlikely to recur.” Moreover, the Doha Declaration on TRIPS, although not binding, explicitly states that countries may use compulsory licensing in order to serve the public health. Just the embodiment of this compulsory licensing policy in TRIPS could be used by proponents of state compulsory licensing to show the legitimacy of such legislation.

Furthermore, based on Article 31 of TRIPS, proponents may argue that their health situation meets all the necessary criteria to compel licenses, and thus is not contradictory to TRIPS nor the U.S. federal government’s position during the TRIPS negotiations. Proponents could point to The District of Columbia’s recently passed legislation as an example that provides for “just compensation” to be paid to the patentee and that any requirement to negotiate was “waived” in the face of a “national emergency” to provide the poor with life-saving therapies for terminal illnesses. Proponents could argue that D.C.’s legislation could be tailored to meet the remaining Article 31 requirements thereby placing the legislation within the treaty’s limited exception to patent protection. Finally, proponents might contend that the pharmaceutical companies are engaged in monopolistic behavior by pricing the drugs without the hindrance of any market competition; thus, any rationale that D.C.’s proposed legislation is in conflict with TRIPS is further strained.

Opponents of compulsory licensing statutes could point out that the U.S. adamantly opposed compulsory licensing statutes as undermining intellectual property protection, and the U.S. has reiterated that position numerous times in response to member nations’ attempts to run end-arounds of valuable intellectual property rights, such as:

- When South Africa threatened to use the compulsory licensing provision of TRIPS to allow its Health Minister to issue compulsory licenses for AIDS treatments, the U.S. immediately considered such a proposal as a violation of intellectual property standards under TRIPS, and counter-threatened with trade sanctions.
- When Brazil gave indications of granting compulsory licenses of AIDS treatments in cases of national emergency or public interest, the U.S. brought a complaint to the WTO (withdrawn in the face of mounting international public pressure).

¹³ It should be noted at the outset that U.S. drug companies do not have a “monopoly” in the classic sense of the word, nor are they acting anti-competitively when pricing drugs. The relevant market of any drug cannot be defined simply by the drug itself, but rather as all treatments of the same disorder. In fact, were a drug company to engage in anticompetitive practices, it would likely shift market share to other alternatives within the industry.

¹⁴ This restriction has been somewhat relaxed since a WTO decision in August 2003 to allow generic exportation under very strict conditions, although the U.S. did not partake in this decision, and thus cannot accept importation of compulsory licensed generics.

Opponents could also point to the U.S. Institute for Policy Innovation's report that stated legislation like that in Brazil would be "one way to ensure that the companies whose patents are broken will not be selling their next generation AIDS drugs, or any other medications for that matter, in Brazil." (Ubirajara Regis Quintanilha Marques *et al.*, *Brazil's AIDS Controversy: Antiretroviral Drugs, Breaking Patents, and Compulsory Licensing*, Food and Drug Law Journal, Vol. 60, No. 3, pp. 471-477 (2005) quoting Institute for Policy Innovation, Necessity Breeds Invention (Protection), TechBytes 2.14 (Apr. 15, 2005), accessible at <http://www.ipi.org> (last visited Aug. 4, 2005).) Opponents might also use the same or similar reasons as provided in the report to show compulsory licensing statutes, whether state or national, would mostly harm U.S. drug companies (*e.g.*, possibly coinciding with attacks under the commerce clause as a substantial burden on interstate commerce). Opponents may also point to the U.S. federal government's opposition to compulsory licensing of pharmaceuticals, even in the face of a worldwide crisis, as ammunition for arguments that state compulsory licensing legislation should be preempted.

III. CONCLUSION

Constitutional requirements provide support for both sides of this debate. Proponents of compulsory licensing statutes can point to the constitutional requirements under eminent domain and procedural due process as sufficient safeguards to protect the same bargain contemplated by Congress in passing the Patent Act of 1952, and thereby attempting to nullify the preemption arguments raised by opponents of such compulsory licensing statutes. Opponents of compulsory licensing statutes can point to the Supremacy Clause and the commerce clause to show that compulsory licensing statutes are preempted by federal law and provide a significant adverse affect on interstate commerce such as to make them unconstitutional, regardless of the compensation, if any, provided in the state licensing scheme.

Greater access to affordable healthcare is a noble and worthwhile pursuit, but state regulation of federally granted patent rights should not be the solution to this problem. Compulsory licensing schemes in the forms currently being considered are unconstitutional, running afoul of the Supremacy and Takings Clauses and conflicting with federal laws. Such programs have broad sweeping economic repercussions that ultimately would cost citizens far more than they would save, and could have ripple effects through some of the most profitable and important industries in the United States.