



THE IRA'S PROPERTY RIGHTS RAMIFICATIONS: DRUG-PRICE "NEGOTIATION" MEETS THE TAKINGS CLAUSE

by Michael M. Berger

When Congress passed the Inflation Reduction Act (IRA), one of the things it sought to do was compel the reduction of the prices government pays for prescription drugs through the Medicare program. Congress did that through a process the IRA refers to as "negotiation," although no one with an understanding of the art of negotiation would recognize it as such. In an IRA negotiation, the government proposes what it calls the "maximum fair price" (MFP) for a drug. The developer/manufacturer is allowed to counter, and the government responds. At the end of the process, the government then imposes the MFP of its choice. There is no bargaining. There is no appeal. Nor can the manufacturer simply walk away from the deal. Under the IRA, a pharmaceutical developer that refuses to accept the government's MFP is subject to ruinous "excise taxes" and penalties.

One of the issues raised in some of the lawsuits challenging the IRA is that the provision violates the Takings Clause of the Fifth Amendment. That is the guarantee that government will not take private property for public use without just compensation. This LEGAL BACKGROUNDER will provide an overview of that issue and the reasons why the Fifth Amendment stands in the way of what Congress seeks to do with the IRA.

The underlying facts are fairly simple to state. Pharmaceutical companies have spent (and continue to spend) billions of dollars developing drugs. That process takes years before any drug can be successfully designed, tested, approved, and marketed. Most such efforts fail. Thus, the investment required in the overall process of creating new drugs is, to put it mildly, huge. The companies' investments are protected because, when they succeed, they are issued patents for their products, guaranteeing them the exclusive right for a period of years to sell the few discoveries that successfully run the gauntlet of federal approval. Exclusivity is critical. Without that guarantee, anyone could simply copy the formula for a drug that cost its producer billions of dollars to create and produce it on its own. The inventor of the formula, for all its investment, would recover nothing.

Congress' goal is not entirely altruistic. The federal government pays for the bulk of the cost of the most expensive drugs on the market through Medicare. See *Sanofi Aventis U.S. LLC v. U.S. Dep't of Health & Human Servs.*, 58 F.4th 696, 699 (3d Cir. 2023). In an effort to reduce the cost of that program, Congress authorized the Secretary of the Department of Health and Human Services to "negotiate" price reductions. We use the word "negotiate" advisedly, because that is the term Congress carefully chose, although it is hardly a true negotiation. The verb "negotiate" means "[t]o communicate or confer (with another or others) for the purpose of arranging some matter *by mutual agreement*; to discuss a matter with a view to some *compromise* or settlement." Oxford English Dictionary (3d ed. 2003) (emphasis added). Nobody would describe a process in which one party can impose its wishes unilaterally on the other as a "negotiation." It is hardly a process by which to arrive at a "mutual agreement."

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Moreover, since the process is unlike any typical negotiation, it raises numerous problems. Many of those problems have to do with the absence of due process of law, and those are covered in the several lawsuits already on file. This paper will focus on the takings issue and leave the due process discussion to others.

The takings issue analysis begins with the fact that constitutional protection is accorded to “private property.” When a pharmaceutical company obtains a patent for one of its creations, does it have a property interest capable of being protected by the Constitution? If not, then there is no case. However, Supreme Court cases dating back more than a century make it clear that patents are private property entitled to constitutional protection.

We should probably start with this question: What is a patent and why should it be protected? The idea of granting and protecting patents is to encourage those with inventive minds to exercise their talents. As the Supreme Court expressed it, “[t]he federal patent system ... embodies a carefully crafted bargain”—in return for “the creation and disclosure of new, useful, and nonobvious advances in technology and design,” the inventor receives “the exclusive right to practice the invention for a period of years.” *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 150–51 (1989). “The object of the patent law is to secure to inventors a monopoly of what they have actually invented or discovered.” *Topliff v. Topliff*, 145 U.S. 156, 171 (1892). “The encouragement of investment-backed risk is the fundamental purpose of the patent grant.” *Patlex Corp. v. Mossinghoff*, 758 F.2d 594, 599 (Fed. Cir. 1985). See *Ruckelshaus v. Monsanto*, 467 U.S. 986, 1003–04 (1984) (citing Blackstone and Locke for the proposition that “property” subsumes all things that arise from “labour and invention”).

The early cases between inventors and the federal government were thus treated as implied contract cases, the theory being that the government would surely not set out to steal private property and thus would be held contractually bound to pay for anything it had taken. In *United States v. Palmer*, 128 U.S. 262 (1888), for example, the owner of patented military equipment demonstrated it to the War Department. The Department decided to use the equipment for the Army. The Court held that the patent’s owner possessed a property interest in the patent that the government could not appropriate without payment. The Constitution demanded that result.

Similar cases are collected in *William Cramp & Sons v. International Curtis Marine etc. Co.*, 246 U.S. 28 (1918), where the Court summarized the settled law as having been “indisputably established” by 1910 thus: “rights secured under the grant of letters patent by the United States were property and protected by the guarantees of the constitution and not subject therefore to be appropriated even for public use without adequate compensation.”

Modern cases have continued this recognition. See, e.g., *Horne v. Dep’t of Agriculture*, 576 U.S.350, 359 (2015) (patent “confers upon the patentee an exclusive property in the patented invention”); *Hartford-Empire Co. v. United States*, 323 U.S. 386, 415 (1945) (“That a patent is property . . . has long been settled.”) Responding to recent arguments that patents are “public rights” and somehow unprotected as in the past, the Supreme Court concluded forcefully that treating patents as “public rights” for some purposes does not mean that “patents are not property for purposes of the Due Process Clause or the Takings Clause.” *Oil States Energy Servs., LLC v. Greene’s Energy Group, LLC*, 138 S. Ct. 1365, 1379 (2018).

Patents, in other words, are property subject to the protection of the Fifth Amendment’s Takings Clause. The consequence is that the owners of patents are entitled to the same protections as other property owners. Although the Takings Clause most often arises in the context of real property, its requirements apply to other forms of property as well: “The government has a categorical duty to pay just compensation when it takes your car, just as when it takes your home.” *Horne v. Dep’t of Agric.*, 576 U.S. 350, 358 (2015) (confiscation of raisins was a Fifth Amendment taking).

The fundamental point of the Fifth Amendment is that it protects all forms of property from all forms of governmental interference. Reviewing the Supreme Court's takings jurisprudence, it is clear that a taking is not defined by the particular means adopted by the government. The centrality of the Takings Clause is that the use of private property cannot be substantially interfered with. Thus, the Supreme Court has found takings in direct government acquisitions, *Berman v. Parker*, 348 U.S. 26 (1954); flooding cases (both intended, *United States v. Dickinson*, 331 U.S. 745 (1947) and unintended, *Pumpelly v. Green Bay Co.*, 13 Wall. (80 U.S.) 166 (1872)); navigable servitudes, *Kaiser Aetna v. United States*, 444 U.S. 164 (1979); aircraft overflights, *United States v. Causby*, 328 U.S. 256 (1946); mining regulation, *Pennsylvania Coal Co. v. Mahon*, 260 U.S. 393 (1922); and temporary direct condemnations, *Kimball Laundry Co. v. United States*, 338 U.S. 1 (1949); *United States v. Petty Motor Co.*, 327 U.S. 372 (1946); *United States v. General Motors Corp.*, 323 U.S. 373 (1945). What connects those cases is that some form of government action took private property, either in whole or in part. See *First English Lutheran Church v. County of Los Angeles*, 482 U.S. 304, 315-16 (1987) (adopting the rationale in *San Diego Gas & E. Co. v. City of San Diego*, 450 U.S. 621, 657 (1981) (Brennan, J., dissenting)).

The key is governmental interference with the property owner's ability to make economically beneficial or productive use of the property. *Lucas v. South Carolina Coastal Council*, 505 U.S. 1003. A taking occurs when government action deprives a property owner of the "rights 'to possess, use and dispose of'" its property. *Loretto v. Teleprompter Manhattan CATV Corp.*, 458 U.S. 419, 435 (1982). The Fifth Amendment's just compensation guarantee is concerned not with the niceties of legal form, but with the practical impact of government actions on the owners of private property. See *United States v. Dickinson*, 331 U.S. 745, 748 (1947) ("Constitution is intended to preserve practical and substantial rights, not to maintain theories") For "the Constitution measures a taking of property not by what a State says, or by what it intends, but by what it *does*." *Hughes v. Washington*, 389 U.S. 290, 298 (1967) (Stewart, J., concurring) (emphasis in original); see also *Davis v. Newton Coal Co.*, 267 U.S. 292, 302 (1925) ("The taking was for a public use. The incantation pronounced at the time is not of controlling importance; our primary concern is with the accomplishment.")

Once that threshold has been crossed, the Fifth Amendment commands compensation. "Government action that works a taking of property rights *necessarily* implicates the 'constitutional obligation to pay just compensation.'" *First English*, 482 U.S. at 315.

Which brings us to the question of how that body of takings law impacts the government's attempt to transfer pharmaceutical patent rights from their owners to either the government or the eventual customers. The answer is the same regardless of whether viewed from the standpoint of the governmental taker or the eventual user. As the Supreme Court put it in *Cedar Point Nursery v. Hassid*, 141 S. Ct. 2063, 2072 (2021), a taking occurs whether the government takes property "for itself or someone else."

Although the Supreme Court has permitted property and wealth redistribution schemes in the past, it has never done so unless the party whose property was being taken was compensated. Indeed, the presence of compensation has been the key to upholding such schemes. *Hawaii Housing Authority v. Midkiff*, 467 U.S. 229 (1984); *Berman v. Parker*, 348 U.S. 26 (1954). As the Court put it in *Berman*, when explaining why it was permitting a forced transfer of property from one citizen to another through the government's coercive eminent domain power, "[t]he rights of these property owners are satisfied when they receive that just compensation which the Fifth Amendment exacts as the price of the taking." 348 U.S. at 36.

When Congress enacts legislation that takes property with no intent to provide compensation, the legislation is invalid. *Hodel v. Irving*, 481 U.S. 704 (1987). The IRA plainly is designed to take a substantial property interest from the pharmaceutical companies and transfer it to the government. After all, the statute mandates that the "negotiations" regarding price reductions *must* result in a reduction of no less than 25%,

and perhaps as much as 60%. And this is to be done in complete disregard of the market value of the drugs or the way in which the market would have (indeed, has until now) determined both the value of the product and its price.

The consequence of the IRA scheme is to take pharmaceuticals' patent rights for public use without just compensation. The latter term has been steadily defined as the "fair market value" of the property taken. The IRA does not even make a pretense of providing fair market value. It is openly based on the premise that the price of certain prescription drugs *must* be radically reduced below market value to what the IRA euphemistically calls the "maximum fair price." As noted earlier, that price will be established not through any sort of actual bargaining or discussion, but by governmental fiat.

Thus, in place of the market system that has prevailed until now under the aegis of Medicare, the IRA will strip the pharmaceutical companies of real indicia of ownership. That goes against the constitutional grain. "[A] sovereign 'by ipse dixit, may not transform private property into public property without compensation ... This is the very kind of thing that the Taking Clause of the Fifth Amendment was meant to prevent.'" *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 1012 (1984). And yet, that is the very kind of thing that the IRA seeks to impose.

The government believes it can do this because participation in Medicare is "voluntary," i.e., no one forces the pharmaceutical companies to participate in the program and sell their product to the government. Under that view, the government is free to dictate the price it will pay. That misses the point. Regardless of the voluntariness of the program, private property cannot be confiscated for public purposes. The government has no such right or power. In discussing the constitutional protection of property, the Supreme Court routinely starts from the premise that "property" is not merely a thing, but a group of rights (or bundle of sticks), and the taking of any one of them without compensation violates the Constitution. In this context, the patent accorded to any individual drug is a property right that is vouchsafed protection. Part of that right is the right to set the price for which the property will be sold. If the price is initially set too high, then the forces of the market will operate to lower it. That is why takings law focuses on compensating property owners for the fair market value of property taken. To forcibly remove that stick from the bundle of rights—without paying fair market value—violates the Fifth Amendment.

As noted above, the patent laws deliberately grant inventors a limited monopoly as an encouragement to the development of new and useful items, like life-saving drugs. In that sense, the combination of the patent laws with the Fifth Amendment runs contra to any feeling that the government is entitled to interdict this specific monopoly power. *Compare Permian Basin Area Rate Cases*, 390 U.S. 747, 769–70 (1968) (purpose of Natural Gas Act was to *protect consumers* against monopoly) with *Topliff v. Topliff*, 145 U.S. 156, 171 (1892) (purpose of patent laws is to *provide inventors* with limited monopoly power). In other words, "[t]he [patent] monopoly is a property right" *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 730 (2002). "Voluntary" participation in the program cannot undercut the combined force of the patent laws and the Fifth Amendment.

Too much constitutional jurisprudence stands in the government's way. In light of settled takings law, the government cannot simply decide to slash the value and utility of recognized private property, confiscating the property for its own use.