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HOUSE COMMITTEE ON THE JUDICIARY
SUBCOMMITTEE ON
COURTS, CIVIL LIBERTIES AND
THE ADMINISTRATION OF JUSTICE
ON H.R. 3605, THE PROPOSED AMENDMENTS
TO THE FOOD, DRUG, AND COSMETICS ACT
AND THE PATENT ACT

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H.R. 3605, if enacted, would amend both the Food, Drug and Cosmetics Act and, more importantly here, the Patent Act.[1] This testimony is addressed to a single provision of the proposed legislation: section 202. Simply put, that section would permit any person to "make, use, or sell" a patented drug for the purpose of developing data for obtaining FDA approval of new drug applications. As applied to future drug patents, section 202 raises important policy issues for Congress. My concern is with section 202 insofar as it would apply to <u>existing</u> patents.

Section 202 radically alters existing law. Section 271(a) of the Patent Act, 35 U.S.C. § 271(a), presently provides that:

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[1] This statement has been prepared at the request of a group of research-based pharmaceutical manufacturers. But the views expressed are entirely those of the author.

> [W]hoever without authority makes, uses or sells any patented invention, within the United States during the term of the patent therefore, infringes the patent.

There is no doubt that, during the life of an existing patent, section 271(a) presently bars any drug manufacturer from making, using or selling a patented drug for the purpose of taking the statutory and regulatory steps necessary to market a drug equivalent to the patented drug. Roche Products, Inc. v. Bolar Pharmaceutical Co., ___ F.2d ___ (Fed. Cir. 1984). This is but an aspect of the central prohibition accorded by the patent during its lifetime: the patent holder's right to exclude *any* use of the patent hostile to his economic interest. Thus, a generic drug manufacturer may not manufacture, use or sell a patented drug for federally mandated pre-marketing tests. *Roche*, *supra*. Section 202 would reverse that result. But, if applied to existing patents, section 202 is in my opinion a taking of property without just compensation, contrary to the fifth amendment to the Constitution of the United States.

I.

The Constitution grants Congress power "to promote the Progress of Science and useful Arts by securing for limited times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries." U.S. Const. art. 1, § 8, cl. 8. This power was designed to benefit the public by encouraging inventions and useful writings. But, equally plainly, these benefits are to be generated through "encouragement of individual effort by personal gain." Mazer v. Stein, 347 U.S. 201, 219 (1954). As the Framers understood, "the public good fully coincides . . . with the claims of individuals." The Federalist, No. 18 (Madison). "The patent laws promote . . . progress by offering inventors exclusive rights for a limited period as an incentive for their inventiveness and research efforts." Diamond v. Chakrabarty, 447 U.S. 303, 307 (1980) quoting, Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470, 480-81 (1974). Thus, as the Supreme Court has observed on recent occasion, while the patent and copyright laws

> perhaps regard the 'reward to the owner [as] a secondary consideration' . . . but they were 'intended definitely to grant valuable, enforceable rights' in order to afford greater encouragement to the production of works of benefit to the public.

Zacchini v. Scripps-Howard Broadcasting Co., 433 U.S. 562, 577 (1977) (citations omitted). This recognition simply confirms the express terms of the Patent Act itself, which provides that "patents shall have the attributes of personal property." 35 U.S.C. § 261. Those attributes include an exclusive right to make, use and sell the patented product. More simply, "the essence of a patent right is the right to exclude others from profiting by a patented invention." Dawson Chemical Corp. v. Rohm & Haas Co., 448 U.S. 176, 215 (1980).[2]

It is, accordingly, plain that neither the government nor private parties are entitled to use the patent during its life without the owner's consent. "That a patent is property, protected against appropriation both by individuals and government, has long been settled." Hartford-Empire Company, 323 U.S. 386, 415 (1945). Indeed, an unbroken line of decisions makes plain that "the government cannot, after the patent is issued, make use of the improvement any more than

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[2] "It has been the judgment of Congress from the beginning that the sciences and the useful arts could be best advanced by giving an exclusive right to the inventor . . . . The language of complete monopoly has been employed." Continental Paper Bag Company v. Eastern Paper Bag Company, 210 U.S. 405, 429 (1908).

a private individual, without license of the inventor, or making him compensation." Cammeyer v. Newton, 94 U.S. 225, 235 (1876); Solomons v. United States, 137 U.S. 342, 346 (1890); see also Belknap v. Schild, 161 U.S. 10, 15-16 (1890). As the Court put it in United States v. Burns, 79 U.S. 246, 252 (1871):

> That the government of the United States, when it grants letters-patent for a new invention or discovery in the arts, confers upon the patentee an exclusive property in the patented invention which cannot be appropriated or used by the government itself, without just compensation, any more than it can appropriate or use without compensation land which has been patented to a private purchaser, we have no doubt. . . . The United States has no such prerogative as that which is claimed by the sovereigns of England, by which it can reserve to itself, either expressly or by implication, a superior dominion and use in that which it grants by letters-patent to those who entitle themselves to such grants. The government of the United States, as well as the citizen, is subject to the Constitution; and when it grants a patent the grantee is entitled to it as a matter of right, and does not receive it, as was originally supposed to be the case in England, as a matter of grace and favor.

See also United States v. Palmer, 128 U.S. 262, 271 (1888). The fact that the government has a need to appropriate the patent or deems it desirable to do so is not sufficient. The Constitution requires that there be compensation for any appropriation. "The title of a patentee is subject to no superior right of the Government." United States v. Dubilier Condenser Corp., 289 U.S. 178, 189 (1937).

These long settled principles make plain that the property secured by the patent is protected by the taking clause. Of course, this is not to say that all legislation affecting outstanding patents is void. McClurg v. Kingsland, 42 U.S. 202, 206 (1844). For example, no one supposes that legislation prohibiting the sale of goods found to be harmful is invalid simply because the goods are manufactured pursuant to an existing patent. But it is equally plain that government legislation "may not take away the rights of property in existing patents." Id. Thus, retrospective legislation "can have no effect to impair the right of property then existing in a patentee. . . ." Id. That "right of property," it must be emphasized, is the patentee's exclusive power to make, use and sell the patented invention during the lifetime of the patent. 35 U.S.C. §§ 154 and 271(a). This right may not be appropriated by the government. And, it is, of course, clear that if the government cannot take property without compensation, it cannot avoid that constitutional bar by authorizing private parties to effectuate the taking. E.g., Loretto v. Teleprompter Manhattan CATV Corp., 458 U.S. 419, 427-28, 432-33, n.9 (1958). The Court's very recent decision in Ruckelshaus v. Monsanto Co., 52 U.S.L.W. 4886 (June 26, 1984) confirms this principle in strong terms.

II.

Section 202's animating premise seems to be a dissatisfaction with the length of time that it takes a generic drug manufacturer to be able to market his drugs because of FDA regulatory requirements. The basis for that dissatisfaction is not altogether apparent. FDA approval requirements seem to result in about a two-year delay in marketing a generic drug, Roche, supra at 13, a regulatory delay substantially less than that usually experienced by the pioneer drug manufacturer whose patented drug is copied. Roche, supra at 12-13. How the conflicting interests of pioneer and generic drug manufacturers are best accommodated in the future is a matter for careful legislative attention. But to materially interfere with existing patents works a considerable injustice to the holder of the pioneer patent who, as has been noted, has himself not only undertaken all the development risks, but who has already suffered appreciable delay in securing FDA approval.

What is more, such a retroactive application would appear to raise very considerable problems as a taking without compensation.

The core of the protection secured by the patent laws is the right to exclude others from use of the patent during the life of the patent. In exchange for granting the invention to the public at the expiration of the patent, the patent holder is permitted to prohibit any use of the patent that is hostile to his patent interests. This includes the right to bar a potential competitor from making <u>any</u> use of the patent that would move him closer to the competitive starting gate at the expiration of the patent. During the period of the patent, competitors must keep hands off the patented invention. The fact that at the patent's expiration date the potential competitor must then clear additional hurdles before mounting a competitive challenge, such as obtaining regulatory approval, is irrelevant to the existing patent right. This additional delay is not caused by the patent, nor does it amount to "an extension of the patent" in any legal sense. The delay is simply a competitive start-up cost imposed by the government wholly apart from the patent.

In its retroactive aspect, section 202 cuts deeply into the protection accorded by the patent. In effect, section 202 reallocates part of the patent holder's property to his competitors, a reassignment of property from the pioneer drug patent holder to his generic drug competitors. I assume that this reallocation could be justified as serving a plausible public purpose, Housing Authority v. Midkiff, 466 U.S. ___ (1984); Ruckelshaus v. Monsanto Co., 52 U.S.L.W. 4886 supra at 4893. But if the reallocation amounts to a "taking," just compensation must be made. Midkiff and Monsanto make that plain. See also Loretto v. Teleprompter Manhattan CATV Corp., 458 U.S. 419, 425 (1982) ("It is a separate question, however, whether an otherwise valid regulation so frustrates property rights that compensation must be paid."). However, we cannot minimize the complexities of meeting the "just compensation" standard. Just compensation "must be a full and perfect equivalent of the property taken," Monongahela Navigation Co. v. United States, 148 U.S. 312, 326 (1893). The owner must be put in as good a position pecuniarily as if his property had not been taken. United States v. Reynolds, 397 U.S. 14, 16 (1970); United States v. Miller, 317 U.S. 369, 373 (1943).

III.

Thus, the critical issue is whether application of section 202 to existing patents amounts to a taking. The law governing whether or not a "taking" has occured is complex, often turning on an ad hoc factual appraisal. Ruckelshaus v. Monsanto Co., supra at 4891. Nonetheless, existing case law strongly suggests that section 202 would amount to a partial taking of existing patents.

There can be no pretense that, in its retrospective application, section 202 would be a rectifying noxious use of the patent, or that the existing patents are accorded such additional rights under H.R. 3605 that there is an "average reciprocity" between the new benefits and burdens. Nor is section 202 simply the destruction of one important feature of the property right, Andrus v. Allard, 444 U.S. 51, 65-66 (1979), in order to prevent illegal use of the property, such as a prohibited trade in certain goods. Id. at 66-67. Rather, section 202 represents an effort to cut into the core of the protection secured by the patent, the right to exclude, and to permit use by the patent holder's competitors.

In Kaiser Aetna v. United States, 444 U.S. 164 (1979), the Court held that the taking clause precluded the government from creating without compensation a public right of access to a former inland pond that had been dredged and opened to a bay and ocean for use as a private marina. The Court said that "what petitioners now have is a body of water that was private property under Hawaiian law, . . ." Id. at 179. In these circumstances, the Court said, the "'right to exclude,' so universally held to be a fundamental element of the property right, falls within the category of interests that the Government cannot take without compensation." Id. at 179-80.

Kaiser Aetna is persuasive here; for there, as here, the government would simply take the prior right and assign it to others. Indeed, here the reassignment is not to the public generally but to the patent holder's competitors. Thus, this is not a situation where all that would occur is a narrowly focused, limited, temporary invasion of the patentee's right without real economic consequences to the economic interests secured by the patent. See Loretto v. Teleprompter Manhattan CATV Corp., supra, 458 U.S. at 433-34. See also Pruneyard Shopping Center v. Robbins, 447 U.S. 74 (1980), in which Kaiser Aetna was further elaborated and the Court emphasized that it was a case where impairment of the right to exclude interfered with the owner's "reasonable investment-backed expectations." Id. at 83-84.

Even if section 202 in its retroactive reach could be viewed as other than an outright appropriation of the existing right to exclude and somehow characterized as a regulation, its impact would have severe consequences to the existing patent holders, causing damage to their reasonable investment-based expectations. Even purely "regulatory" statutes having such an impact raise significant issues under the taking clause. Penn Central Transportation Co. v. United States, 438 U.S. 104 (1978); Robbins, supra. But the crucial point to my eye is that section 202 is difficult to characterize fairly as a regulation, with an "incidental" impact upon existing property. Section 202 simply takes one of the recognized incidents of ownership, the right to exclude all use until the patent expiries, and partially reassigns it, not just to another person or to the public generally but to the patent holder's competitors. No one, least of all the generic drug manufacturers who would benefit so heavily by section 202, disputes that what is reassigned has important economic impact on the patent holder's "reasonable investment-backed expectations." Thus an "examination . . . into such factors as the character of the government action, its economic impact, and its interference with reasonable investment-backed expectations," Robbins, supra, at 83; Loretto, supra, at 432, all point in the direction of a taking.[3]

The Supreme Court's decision this week in Ruckelshaus v. Monsanto Co., 52 U.S.L.W. 4886 (June 26, 1984) completely settles the question of whether the application of section 202 to existing patents would constitute a taking. In that case, the Court held that trade secret data which had been submitted by Monsanto

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[3] In this respect, section 202 seems analogous to a physical appropriation of real or personal property. Loretto v. Teleprompter Manhattan CATV Corp., 458 U.S. 419 (1982). "Property rights in a physical thing have been described as the rights 'to possess, use and dispose of it' . . . to the extent that the government permanently occupies physical property, it destroys each of these rights." Id. at 435. So here also. The right secured by the patent -- to make, use and sell -- are all subject to permanent invasion, to what amounts to an easement in the patent holder's competitors. Even if not perfect, the analogy is suggestive. For it is clear that the protection of the clause is not confined to relief against physical appropriation, but rather to the "group of rights inhering in the citizen's relation to the physical thing, as the right to possess, use and dispose of it. . . ." United States v. General Motors, 323 U.S. 373, 377-78 (1945), quoted with approval in Pruneyard Shopping Center v. Robbins, 447 U.S. 74, 87 n.6, and Loretto, 458 U.S. at 435. Thus, in considering whether there is an invasion of the patent right, "reference to the uses for which the property is suitable, having regard to existing business or wants of the community," Bloom Co. v. Patterson, 98 U.S. 403, 408 (1908), must be made. Section 202's impact on existing patents is analogous to the taking of an easement in property, for which compensation must be paid.

to the Environmental Protection Agency was property within the meaning of the Fifth Amendment taking clause. Since the applicable statute in that case guaranteed Monsanto that the data submitted between the years 1972 through 1978 would be confidential and exclusive, the Court found that this formed "the basis of . . . Monsanto's reasonable investment-backed expectation with respect to its control over the use and dissemination of the data it had submitted." Supra at 4892.

The Court reiterated that, "The right to exclude others is generally 'one of the most essential sticks in the bundle of rights that are commonly characterized as property.'" (Citation omitted.) It proceeded to apply that principle to trade secrets, noting that "the right to exclude others is central to the very definition of the property interest." Id. It denied the government's claim that post-1978 amendments to the statute gave the agency a retrospective right to preempt Monsanto's property in its trade secrets. The notion that the government could "pre-empt" existing property rights in trade secrets was flatly rejected as inconsistent with the very thing that the taking clause of the Fifth Amendment was meant to prevent. Id. at 4893. No argument is needed to show that an attempt retrospectively to impair patent rights is entitled to protection that is at least as great as that which the Supreme Court accorded to trade secret property in Monsanto.

IV.

It bears emphasis that nothing in the Supreme Court's recent decision in Pension Benefit Guaranty Corp. v. Gray & Co., 467 U.S. ___, 52 U.S.L.W. 4810 (June 19, 1984), is inconsistent with the foregoing analysis. There the Court upheld retroactive increases in the liability of employers participating in multi-employer pension plans. Writing for the Court, Justice Brennan rejected a challenge that retroactive application of the statute violated the due process clause of the fifth amendment, saying that the clause is satisfied "simply by showing that the retroactive application of the legislation is itself justified by a rational legislative purpose." 52 U.S.L.W. 4814. Other distinctions aside, it is important to emphasize that Pension Benefit did not involve any question under the Taking Clause. Not a line in the opinion even adverts to that clause. But like the contract clause, see id.

at 4814,[4] the Taking Clause imposes restrictions against retroactive legislation beyond those contained in the due process clause. Justice Brennan himself made that clear in San Diego Gas and Electric Company v. San Diego, 450 U.S. 621 (1981). At issue was whether a state whose regulation amounted to a taking was obligated to pay damages for the period during which the regulation remained in effect. The Court dismissed the appeal as not being properly before it. Justice Brennan authored a four-person dissent, id. at 636, which Justice Rehnquist indicated he would have had "little difficulty in agreeing with much of what is said" if the case were properly there, id. at 633-34. Justice Brennan concluded that the state must pay compensation. In the course of his

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> "Second, it is suggested that we apply constitutional principles that have been developed under the Contract Clause, Art. I, § 10, cl. 1 ("No State shall . . . pass any . . . Law impairing the Obligation of Contracts. . . ."), when reviewing this federal legislation. . . . We have never held, however, that the principles embodied in the Fifth Amendment's Due Process Clause are coextensive with prohibitions existing against state impairments of pre-existing contracts. . . . Indeed, to the extent that recent decisions of the Court have addressed the issue, we have contrasted the limitations imposed on States by the Contract Clause with the less searching standards imposed on economic legislation by the Due Process Clauses."

opinion, Justice Brennan drew a clear distinction between challenges based on due process and challenges based on the taking clause. Id. at 648-50, and n.14. See also Justice Black's opinion in Penn Central Trans. Co. v. New York City, 438 U.S. 104, 120-22, and n.25 (1978); and see, e.g., Pruneyard Shopping Center v. Robbins, 447 U.S. 74, 82-84 (1980) (distinguishing between taking and due process challenges); Loretto v. Teleprompter CATV Corp., supra at 425.

Any conceivable doubt on this point is put to rest by the decision in Ruckelshaus v. Monsanto Co., 52 U.S.L.W. 4886, supra. In holding that retrospective application of a statute permitting the disclosure of trade secrets would amount to a taking, the Court did not even cite Pension Benefit, correctly perceiving that the latter case involved only the due process, not the taking clause.

V.

We have here a situation of gross injustice. Existing patent holders have an absolute right to exclude hostile use by others. Under section 202 as it now stands, part of that right would be taken from them, and given to their competitors. This non-compensated transfer is tantamount to a claim, squarely rejected in Webb's Fabulous Pharmacies, Inc. v. Beckwith, 449 U.S. 155, 164 (1980), where the Court held that the government, "by ipse dixit, may not transform private property into public property without compensation . . . [even if only] for [a] limited duration." See also Loretto v. Teleprompter Manhattan CATV Corp., supra, 458 U.S. at 439. As the Supreme Court said in Beckwith, "[t]his is the very kind of thing that the Taking Clause of the Fifth Amendment was meant to prevent." 449 U.S. at 164; Ruckelshaus v. Monsanto Co., supra, 52 U.S.L.W. at 4893. In these circumstances, therefore, it seems likely that compensation must be paid if section 202 is to affect existing patents. Alternatively, of course, section 202 could be amended to make plain that it is intended to have no impact on the rights secured by existing patents.