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STATEMENT OF NORMAN DORSEN
CONCERNING THE CONSTITUTIONAL ISSUES RAISED BY
SECTION 202 OF THE PATENT EXTENSION PROVISIONS OF
H.R. 3605

My name is Norman Dorsen. I have been on the faculty of New York University School of Law since 1961, and have taught courses in Constitutional Law, Antitrust Law, The Legal Process and Legislation, among others. I am currently Frederick and Grace Stokes Professor of Law. Since 1980 I have also regularly taught as a Visiting Professor at Harvard Law School. I have written several books and law review articles and have often testified before Congress on constitutional issues. I served as President of the Society of American Law Teachers during 1972 and 1973.

From 1976 to 1977 I was Chairman of the Department of Health, Education, and Welfare, Review Panel on New Drug Regulation. Under my direction the Panel produced five volumes of studies on the drug regulation process. Since 1977 I have published articles on the regulatory process in the Annals of Internal Medicine and the Food Drug Cosmetic Law Journal.

I was asked by representatives of a coalition of research based pharmaceutical companies to review Section 202 of the proposed Patent Extension legislation to determine if the bill presents any serious constitutional problems. In my judgment, constitutional problems do exist and they are substantial.

DESCRIPTION OF SECTION 202

Section 202 would reverse existing patent law which now gives the owner of a patent the exclusive right to make, use and sell the patented invention. 35 U.S.C. §§ 154 and 271(a). It would allow a third party to make, use or sell a patented invention for purposes "reasonably related" to the submission of information to obtain premarketing approval under the Food, Drug and Cosmetic Act in order to engage in the commercial manufacture, use or sale of the drug after patent expiration. The constitutional problem arises because Section 202 does not just apply prospectively to patents that will come into being after its enactment, but it also reaches back and takes away exclusive rights of current patent holders. After analyzing the existing statutory rights that will be taken from the patent holder under the bill, I am forced to conclude that Section 202 very likely violates the Fifth Amendment's

prohibition against the taking of property for a public use without just compensation.

THE BOLAR DECISION

Section 202 takes from the patent owner the same patent rights which the Court of Appeals for the Federal Circuit has declared belong exclusively to the owner under the present patent law. In Roche Products, Inc. v. Bolar Pharmaceutical Co., Inc., ___ F.2d. ___, No. 84-560, slip op. (Fed. Cir. Apr. 23, 1984), the court held that Bolar, a generic drug manufacturer, unlawfully infringed a patent owned by Roche when, during the patent term, Bolar used the patented substance to prepare a submission to the Food and Drug Administration for the purpose of enabling Bolar to market the drug after the Roche patent expired. The Court of Appeals agreed with Roche that such "use" by Bolar of Roche's patented drug during the term of the patent grant for the purpose of engaging in federally mandated premarketing tests was part of the exclusive patent grant reserved to the patent owner. Having determined that Bolar's unauthorized use infringed Roche's patent, the Court of Appeals then held that "Roche is entitled to a remedy," in the form of an injunction or damages. Bolar, supra, at 16. It ordered that specific relief was to be fashioned

in the first instance by the District Court to which the case was then remanded and before which it is now pending. In directing that remand, the Court of Appeals recognized that although the infringement involved a small amount of material, "the economic injury to Roche is, or is threatened to be, substantial . . . ." Bolar, supra, at 19. See also Pfizer, Inc. v. International Rectifier Corp., 217 U.S.P.Q. 157 (C.D. Cal. 1982).

IMPACT OF SECTION 202 ON THE BOLAR DECISION

Section 202 of the proposed legislation would reverse the Bolar decision in its entirety, not just for the patent involved in that case, but for all existing drug patents. Indeed, the bill would go beyond the infringing conduct involved in Bolar by making it lawful for an infringer to make and to sell as well as to use the patented substance during the period of the patent grant, if done for the purpose of securing FDA approval of a new drug. It would also reverse existing patent law by prohibiting courts from issuing an injunction against making, using or selling the substance for that purpose, and it would withdraw from the patentee his current right to collect damages for such infringement.

THE NATURE OF THE CONSTITUTIONAL PROBLEM

Because patent rights are a form of property, taking such rights from the owner raises a basic issue under the Fifth Amendment. The Constitution recognizes that from time to time it will be necessary for the government to acquire private property for public purposes, but by requiring "just compensation" for such taking, the Fifth Amendment protects the individual whose property is taken for the common good from being made to carry a burden that should, in fairness, be shared by the community at large. The Supreme Court has described the purposes of this clause in the following terms:

> "[The] Fifth Amendment's guarantee that private property shall not be taken for a public use without just compensation was designed to bar Government from forcing some people alone to bear public burdens which, in all fairness and justice, should be borne by the public as a whole." Armstrong v. United States, 364 U.S. 40, 49 (1960).

We tend to think of civil rights in terms of First Amendment rights of free speech and expression, but the "taking" clause of the Fifth Amendment is also a civil right, one which stands as a bulwark against governmental appropriation of vested property rights.

The Constitution imposes restraints upon government's ability to confiscate property just as it imposes restraints upon government's ability to confiscate our right to speak or the right of a newspaper to publish without censorship.

THE CONSTITUTIONAL POLICY IN SUPPORT OF PATENTS

Any analysis of how Section 202 fits within the Fifth Amendment's "taking" clause must first look at the nature of the property that this bill will affect -- the patent grant.

I am always impressed when reminded by patent lawyers that the Constitution is itself the source of authority for the patent system. Unlike many governmental activities that surround our daily lives, the right to grant patents is not implied from some other general power, but is expressly decreed in Article I, Section 8, and the policy behind that authorization is plainly stated. A patent system is authorized in order "to promote the progress of Science and useful Arts . . . ." In applying Fifth Amendment principles to patent property, it is therefore important to keep in mind that patent grants are a reflection of a public policy that is as old as the Republic and one that has independent

constitutional stature. It is well known that the patent system has been a great success. It has made a major contribution to this country's technological preeminence. The reliance which has been placed on our patent system by inventors and by those who underwrite research and development should not be chilled by retroactively stripping away existing rights.

PATENT GRANTS, INCLUDING EXCLUSIVE USE RIGHTS, ARE PROPERTY RIGHTS PROTECTED BY THE FIFTH AMENDMENT

Patent Rights are Property Rights

Existing patent law declares that a patent is a property right. Title 35, U.S.C. § 261 states: "patents shall have the attributes of personal property." Patents are not only defined as property; they also contain the essential elements of property. By statute, a patent grants its holder the right to exclude others from making, using or selling the patented invention during the term of the patent. 35 U.S.C. §§ 154, 271(a). A patent embodies "the right to dispose of a thing in every legal way, to possess it, to use it, and to exclude everyone else from interfering with it,"[1] which is the definition of property.

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[1] Black's Law Dictionary 1095 (rev. 5th ed. 1979).

Supreme Court rulings unambiguously reaffirm that patents are property rights protected by the Fifth Amendment. In William Cramp & Sons Ship & Engine Building Co. v. International Curtis Marine Turbine Co., 246 U.S. 28, 39-40 (1918), the Court wrote that it is "indisputably established" that "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." Similarly, in Hartford-Empire Co. v. United States, 323 U.S. 386, 415, clarified, 324 U.S. 570 (1945), the Court stated "[t]hat a patent is property, protected against appropriation both by individuals and by government, has long been settled."

The Right of Exclusive Use Is an Integral Component of the Patent Grant and Concomitant Property Right

In exchange for the benefits derived from innovation and invention, society, through a government patent, grants an inventor three co-equal rights: exclusivity of manufacture, exclusivity of use and exclusivity of sale. Each of these rights is necessary for the innovator to reap the commercial fruits of his

creative labor. Because the right to exclude others from its use is the sole source of a patent's economic value, the protection of this trilogy of rights is critical to the viability of the patent system.

The federal courts have long recognized that an infringement of a patent holder's right of exclusive use or manufacture is as fundamental a conversion of property as an infringement of his right of exclusive sale. The unauthorized making of a patented product is an infringment because it allows a competitor to stockpile the product and flood the market immediately following expiration of the patent.[2] Similarly, reconstruction of a patented product involves economic activity directly traceable to the patent. Accordingly, courts have held that reconstruction other than by the patentee or its licensee violates the patentee's exclusive right to make the product.[3]

The right of a patent holder to exclusive use of his invention has also been protected rigorously. As the Supreme Court has put it, "an inventor receives

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[2] See, e.g., Underwood Typewriter Co. v. Elliott-Fisher Co., 156 F. 588, 590 (C.C.S.D.N.Y. 1907); American Diamond Rock Boring Co. v. Sheldon, 1 F. 870, 872-73 (C.C.D. Vt. 1880).

[3] See, e.g., Wilbur-Ellis Co. v. Kuther, 377 U.S. 422, 424 (1964).

from a patent the right to exclude others from its use for the time prescribed in the statute." Continental Paper Bag Co. v. Eastern Paper Bag Co., 210 U.S. 405, 425 (1908).[4] Indeed, it is recognized that, "The very nature of the patent right is the right to exclude others." Smith International, Inc. v. Hughes Tool Co., 718 F.2d 1573, 1581 (Fed. Cir.), cert. denied, 104 S. Ct. 493 (1983). In line with this longstanding policy, the mere testing of a patented product for commercial purposes has been prohibited -- both in connection with pharmaceuticals[5] and other products.[6] The purpose of exclusive use is evident: to preserve all commercially valuable uses for the patentee to exploit as he sees fit.[7] Tests and other uses of a patented product having a commerical purpose reduce the economic potential and value of the patent during its term. Under law all such economic benefits belong to the patent holder.

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[4] See also Aro Manufacturing Co., Inc. v. Convertible Top Replacement Co., Inc., 377 U.S. 476, 484 (1964), where the Supreme Court stated: "unauthorized use, without more, constitutes infringement."

[5] See, e.g., Roche Products Inc. v. Bolar Pharmaceutical Co., Inc., slip op. No. 84-560 (Fed. Cir. Apr. 23, 1984); Pfizer, Inc. v. Int'l Rectifier Corp., 217 U.S.P.Q. 157, 162 (C.D. Cal. 1982.)

[6] See, e.g., Radio Corp. of America v. Andrea, 90 F.2d 612, 614 (2d Cir. 1937) (radio components).

[7] See Kaz Manufacturing Co. v. Chesebrough-Pond's, Inc., 211 F. Supp. 815, 818 (S.D.N.Y. 1962), aff'd, 317 F.2d 679 (2d Cir. 1963).

Even outside the patent area, the Supreme Court has recognized that the right to exclude others from the use of a possession is the touchstone of property. Justice Brandeis wrote that "[a]n essential element of individual property is the legal right to exclude others from enjoying it." International News Service v. Associated Press, 248 U.S. 215, 250 (1918) (dissenting opinion). Recently, in Kaiser-Aetna v. United States, 444 U.S. 164 (1979), the Court ruled that the federal government could not require a privately developed and operated marina to open itself to the use of the general public without the payment of just compensation. The Court held that

> "the 'right to exclude,' so universally held to be a fundamental element of the property right, falls within this category of interests that the Government cannot take without compensation." 444 U.S. at 179-80.

Section 202 seeks to accomplish with pharmaceutical patents precisely the result prohibited by the Supreme Court in Kaiser-Aetna with respect to the marina. It seeks to abridge a patent holder's existing statutory right of exclusive use in a manner which the Court of Appeals for the Federal Circuit -- the specialized appellate court with exclusive jurisdiction over patent

appeals -- characterized as worthy of substantial monetary damages.[8]

Section 202 "Takes" Property In Violation of the Fifth Amendment

The law has long recognized that a "taking" of property can occur even if the intrusion amounts to something less than a physical invasion by the government. Chief Justice John Marshall early pointed out that the Constitution is one of enumeration not definition, and so, like most of the great constitutional clauses, the "taking" clause is not confined to its literal text. Two threads run through the decided cases which explain the meaning of "taking." The first is an outgrowth of the traditional concept, where the government physically strips the property owner of a part of the bundle of rights that constitutes his property interest. The second line of cases does not involve physical takings, but rather takings through governmental regulation of an owner's use of his property where the regulation so frustrates legitimate expectations regarding the economic potential of that property that compensation is required.

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[8] Bolar, slip op. at 11.

Kaiser-Aetna is a leading case in the classical takings line of cases. In that case, the owners of the private pond, who had invested substantial sums to dredge and improve it into a marina, were faced with an effort by the Corps of Engineers to convert the pond into a public aquatic park. Despite the government's claim that its Commerce Clause powers to regulate navigable waters authorized public access, the Court ruled that the government lacked the authority to destroy the owner's right to exclude others from the marina without payment of compensation.

Where such a traditional taking occurs, the fact that only a small fraction of the entire property right is involved does not deprive the owner of Fifth Amendment protection. In Loretto v. Teleprompter Manhattan CATV Corp., 458 U.S. 419 (1982), it was held that a state law which authorized the permanent attachment of cable TV installations on apartment house premises constituted a taking which requires just compensation under the Fifth Amendment, even though the connector occupied only a tiny fraction of the property.[9]

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[9] In Loretto the Supreme Court made it clear that a nominal payment for a compulsory taking cannot meet the "just compensation" mandate of the Fifth Amendment.

In the second line of just compensation cases the law recognizes that takings can occur when governmental regulation prevents an owner from using his property -- even though the government does not physically occupy the property itself or transfer it to a third person. The reasoning underlying these cases is straightforward: where governmental regulation deprives an owner of the use of his property in a way that defeats reasonable investment-based expectations, significant and valuable property rights are effectively "taken" from the owner, bringing into play the protections afforded by the Fifth Amendment.[19] As one would expect, decisions analyzing the effect of such government regulation tend to be highly fact oriented, since the outcome will turn in large part on a determination of the owner's reasonable expectations. But, the rule of law is clear: even a statute which furthers an important public policy will be held to constitute a "taking" where it frustrates distinct and legitimate investment backed expectations.

The leading case is Pennsylvania Coal Co. v. Mahon, 260 U.S. 393 (1922). In that case, Justice Holmes held for the Court that a statute which regulated

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[19] See Penn Central Transportation Co. v. New York City, 438 U.S. 104, 124 (1978).

subsurface mining in a way that effectively deprived the owner of coal mining rights of the right to mine his coal was a "taking." By contrast, when the facts demonstrated that a state statute pursuant to which the Grand Central Terminal was designated a landmark did not interfere with the owner's investment-based expectations as to the use of the property, the Court found that there had been no "taking" even though the landmark statute prevented the terminal building's owners from further developing their property by constructing an office tower atop the terminal. Penn Central Transportation Co. v. New York City, 438 U.S. 104 (1978).

There is a strong basis for concluding that Section 202 would be held to constitute a "taking" both under the reasoning of cases like Kaiser-Aetna, where a direct appropriation and transfer of the owner's rights was involved, and under cases like Pennsylvania Coal, where government regulation frustrated reasonable investment-based expectations.

As to the classic "taking" line of cases, the Bolar decision and other patent and nonpatent cases demonstrate that the right of exclusive use is fundamental to the ownership of patents -- even more than it is for other forms of property, since the sole source of

a patent's value is exclusivity. The economic significance of this right is beyond dispute. The Bolar court expressly stated that the value of the patentee's right to exclusive use for pre-marketing test purposes was substantial. The impressive efforts of the generic pharmaceutical companies to secure passage of Section 202, and the equally vigorous efforts of some of the leading research-based pharmaceutical companies to oppose it, provide perhaps the strongest proof that the rights at stake have great commercial value.

If Section 202 becomes law, the exclusive right to make, sell and use the patented product for pre-marketing tests would be taken from the patentee and transferred to the infringer. Indeed, the taking contemplated by Section 202 is even more offensive than the taking condemned in the Kaiser-Aetna case. There, the government sought simply to give the general public an easement in a private marina. Here, the transfer is from a business to its competitor. Generic pharmaceutical firms will be given a special commercial advantage at the expense of research-based companies, in effect, a free ride to use, make and sell the research-based patentee's invention for a commercial purpose long before the patent expires.

This "free rider" provision underscores the fact that the equities have all run against the proposed Section 202. The company holding the patent funded the product's research and development and incurred costs associated with informing the medical profession and general public of its value and use. Having shouldered all the commercial expense and risk of bringing a new product to market, it is entitled to reap the patent benefits over the full life of its patent. We can assume that the bill seeks to achieve a valid overall purpose, but that objective is no substitute for the Fifth Amendment's requirement of fair treatment to a party whose property is being taken for public purposes.

Alternatively, if one examines the bill under the governmental regulation line of Fifth Amendment cases, the provision also presents serious constitutional problems. The distinct investment-based expectations held by owners of existing patents are founded upon the substantive protections written into the patent statute. The statute as it existed when the patent was granted established the scope of these property rights and expectations -- and it included a 17-year exclusive right to "make" and "use" the patented product. Section 202 withdraws from the patentee a central element

of those rights, and thereby deprives an owner of property in a way that defeats his reasonable expectations.

The Police Power Exception is Inapplicable

Under certain circumstances, governmental regulation in the exercise of its police power to protect the public health, morals and safety can provide an exception to the taking clause of the Fifth Amendment. However, this exception is not coterminous with the reach of the police power and the mere invocation of the police power does not relieve the government of its "just compensation" obligation.

An examination of the police power cases demonstrates that the takings involved all sought to terminate specific nuisances or to halt isolated noxious uses of property that were a danger to the health, morals or safety of the community. Classic instances involved the operation of a brickyard within a residential area;[11] the prohibition of gravel excavation below the water line;[12] the cutting down of infected cedar trees to prevent a spread of the infection to neighboring

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[11] Hadacheck v. Sebastian, 239 U.S. 394 (1915).

[12] Goldblatt v. Hempstead, 369 U.S. 590 (1962).

groves;[13] and the halting of nonessential gold mining during a wartime emergency labor shortage when miners were needed to produce war materials instead.[14]

It is manifest that these cases are radically different from the case presented by Section 202. The property uses that would be affected by Section 202 are not nuisances. Indeed, the patented substances are economically desirable and socially useful, and the exclusivity rights that would be extinguished are consistent with the policy of the Patent Statute and with Article I, Section 8, Clause 8 of the Constitution.

No "Reciprocity of Advantage" Is Present

Section 202 is not analogous to certain zoning ordinances which have not been considered "takings" because they provide an "average reciprocity of advantage." See, e.g., Pennsylvania Coal Co. v. Mahon, 260 U.S. 393, 415 (1922). In these cases, the Supreme Court has held that the zoning regulation at issue did not constitute a "taking" because the property owner was also advantaged by the regulation.

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[13] Miller v. Schoene, 276 U.S. 272 (1928).

[14] United States v. Central Eureka Mining Co., 357 U.S. 155 (1958).

In this respect, a comparison with the Grand Central Terminal case is instructive. In Grand Central, while the owners were prevented by New York's Landmarks Law from building above the Terminal itself they nevertheless received from the government "transferable development rights" to build on nearby parcels. Here the proposed legislation does not grant any such reciprocity. On the contrary, a substantial imbalance is present in this bill between the patent extension section -- Section 201, which with minor exceptions extends patent life only for patents that will come into being after enactment of the bill (thus, most existing patents would not qualify for extension) -- and Section 202, which would apply retrospectively and prospectively and subject every drug patent to the loss of the patentee's exclusive right to use.

Congress Cannot Take Back Property Rights in Patents Simply Because It Created Those Rights

The retroactive repeal of existing patent protection cannot be sustained as an exercise of the independent power of Congress to create patents, because

it accomplishes the very opposite.[15] All property rights are created by the government because it is the government through its laws that permits private property to exist. Congress can no more appropriate by legislative fiat one's rights in a patent than it can appropriate one's rights in land. As the Supreme Court has noted:

> "A patent for an invention is as much property as a patent for land. The right rests on the same foundation, and is surrounded and protected by the same sanctions." Consolidated Fruit-Jar Co. v. Wright, 94 U.S. 92, 96 (1877).

There is thus no constitutionally significant difference between patent rights and other property rights; the Fifth Amendment's prohibition against uncompensated takings is applicable, in full force, to patents and the holder's right of exclusive use associated with that patent.

Similarly, with respect to the Bolar case itself, the legislation would take from Roche its court-determined right to obtain potentially substantial damages from Bolar for conduct held to be patent infringement at the time it occurred.

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[15] This point was made forcefully by Professor Laurence Tribe in his testimony concerning home video recordings. See Home Recording of Copyrighted Works: Hearings Before the Subcomm. on Courts, Civil Liberties and the Administration of Justice of the House Comm. on the Judiciary, 97th Cong., 2d Sess. 1216 (1982).

PROSPECTIVE APPLICATION OF SECTION 202 WOULD AVOID THE "TAKING" PROBLEM

If Section 202 were merely prospective in its application, applying only to patents issued after enactment, the "taking" problem would be avoided entirely. While a retroactive law is not invariably unconstitutional, when retroactivity results in a "taking" of property, the Fifth Amendment is implicated, and if the legislation runs afoul of Fifth Amendment protections, it is unconstitutional.

Even though the Supreme Court recently upheld the constitutionality of a retroactive amendment to the ERISA statute under the Contract Clause where the effective date of the act was geared to the date the legislation was introduced, Pension Benefit Guaranty Corp. v. R.A. Gray & Co., 52 U.S.L.W. 4810 (June 18, 1984), retroactive legislation has, nevertheless, been a well of constitutional problems.[16] One authority

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[16] In United States Trust Co. v. New Jersey, 431 U.S. 1, 21-22 (1977), the Court invalidated a retroactive state statute that impaired preexisting contract rights when less drastic alternatives were available to the legislature. Compare also Lynch v. United States, 292 U.S. 571 (1934) (federal government prohibited from impairing its own contract obligations by legislation that cancelled war risk life insurance policies), and Allied Structural Steel v. Spannaus, 438 U.S. 234 (1978) (declaring invalid a state statute which materially altered the terms of a preexisting pension plan causing a permanent and immediate change in the expectations

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has written that "It is a fundamental principle of jurisprudence that retroactive application of new laws involves a high risk of being unfair." Sands, Sutherland's Statutes and Statutory Construction § 41.02 (4th ed. 1972). The author explains:

> "One of the fundamental considerations of fairness recognized in every legal system is that settled expectations honestly arrived at with respect to substantial interests ought not be defeated." Id. at § 41.05.

Indeed, just this week, House and Senate conferees agreed to eliminate the retroactive feature of the legislation that was the subject of the Pension Benefit decision because of its perceived unfairness. See Cong. Rec. H6683 (June 22, 1984).

Retroactive legislation in the patent area presents a more clearcut case of unfairness than a retroactive pension statute because the government is a party to the patent grant. Patent owners rely on the express terms of the statute and on constitutionally grounded

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[Footnote 16 continued from preceding page]
of the parties), with Home Building & Loan Ass'n v. Blaisdell, 290 U.S. 398 (1934), and Energy Reserves Group, Inc. v. Kansas Power & Light Co., 103 S. Ct. 697, 706-08 (1983) (permitting state legislation that impaired preexisting contracts).

public policy when they disclose their inventions. The issue raised by Section 202's retroactive application has been addressed in earlier judicial decisions. See McClurg v. Kingsland, 42 U.S. (1 How.) 202, 206 (1873) (new patent legislation "can have no effect to impair the right of property then existing in a patentee"); Diebold, Inc. v. Record Files, Inc., 114 F. Supp. 375, 376 (N.D. Ohio 1953) ("The constitutional principle of due process prohibits the retroactive application of the new statute and a resultant invalidation of the plaintiff's patent claims").

To avoid the constitutional difficulties inherent in retroactive legislation, Congress has traditionally been careful to limit the effect of new statutes on existing patent rights. This was most evident in the Patent Act of 1952, which revised and codified the patent laws and repealed prior laws. There, Congress specifically provided that "any rights or liabilities now existing under such [repealed] sections or parts thereof shall not be affected by this repeal." Act of July 19, 1952, c. 950, § 5, 66 Stat. 815.

Whatever validity retroactive legislation may have in other areas of the law, it is plain that such statutes cannot abrogate the protections afforded by

the Takings Clause of the Fifth Amendment. Since Section 202 seeks to accomplish just such an abrogation of Fifth Amendment rights, its constitutionality is seriously jeopardized.

CONCLUSION

In sum, as a matter of constitutional law, Congress without providing just compensation cannot abridge patent and property rights it has conferred and upon which inventors and investors have reasonably relied. This is precisely the aim of Section 202. The rights involved are substantial and the constitutional infirmities significant.