ORAL PRESENTATION 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 Proces and Legislation, among others. I am currently Frederick and Grace Stokes Professor of Law. Since 1980 I have also taught regularly 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's 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-oriented 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.

With the consent of the Committee, I would like to submit a statement for the record that fully expresses the reasons for this conclusion. In this oral presentation, I shall outline the essential elements of the analysis.

1. It is undisputed that patent grants are property rights protected by the Fifth Amendment to the Constitution. Title 35, U.S.C. § 261 states: "patents shall have the attributes of personal property." Supreme Court rulings unambiguously affirm this property right.

2. The right of exclusive use is an integral component of the patent grant and the property right. With particular pertinence to the problem before us, the Court of Appeals for the Federal Circuit, in the recent Bolar decision, has confirmed that protection of this right is necessary for the innovator properly to reap the fruits of his creative labor.

3. Section 202 of the proposed statute would abrogate the right recognized in the Bolar decision 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 approval from the FDA.

4. Section 202 raises a basic issue under the Takings Clause of the Fifth Amendment. This provision requires the government, when it acquires private property for public purposes, to pay "just compensation" for all takings. This provision was designed, in the words of the Supreme Court, "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. U. S., 364 U.S. 40, 49 (1960).

5. This policy has particular force in the realm of patent grants. The Constitution plainly states that the patent system is founded on the public policy "to promote the progress of Science and useful Arts. . . ." The system has been a great success; it has made a major contribution to the 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.

6. Apart from the patent area, the Supreme Court has recognized that the right to exclude others from the

use of a possession is the touchstone of private 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. U. S., 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.

7. 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 interfere with a patent holder's 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. Bolar, slip opinion at 9, 11.

8. Section 202 is also vulnerable under a long line of cases that recognize that takings can occur when government regulation prevents an owner from using his property -- even though the government does not

physically occupy the property or transfer it to a third person. The reason is that deprivation of use defeats an owner's reasonable investment-based expectations. E.g., Pennsylvania Coal Co. v. Mahon, 260 U.S. 393 (1922) (statute which regulated subsurface mining in a way that effectively deprived the owner of a coal deposit of the right to mine was a "taking").

9. 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. This "free rider" provision underscores the fact that the equities all run against the proposed Section 202. We must not forget that the company holding the patent funded the product's research and development and incurred the costs associated with informing the medical profession and general public of its value and use.

10. The police power exception of the Fifth Amendment's Taking Clause is designed to protect the public health, morals and safety. It is inapplicable to Section 202. Police power cases all involve property taken to terminate specific nuisances or dangers to the

community. A patent is neither a nuisance or a danger. Indeed, the Constitution itself recognizes that it is economically desirable and socially useful.

11. Nor is Section 202 analogous to certain zoning ordinances which have not been considered takings because they provide an "average reciprocity of advantage." Mahon, supra at 415. There are two reasons for this conclusion. First, this rather nebulous doctrine has never been applied, as far as I know, to diminish the rights of patents -- which after all are uniquely subject to constitutional protection. Second, the proposed legislation does not grant "average reciprocity of advantage." On the contrary, a substantial imbalance is present in this bill between the patent extension provision in Section 201 and Section 202, which presents the constitutional problem. With minor exceptions, Section 201 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). On the other hand, Section 202 would apply retrospectively to deprive every patentee of his exclusive right to use. In other words, the economic benefits of patent extension are speculative and not evenly shared, while the negative economic impact on the property rights of patentees from Section 202 is certain and universal.

12. Although retroactive laws are not invariably unconstitutional, retroactive legislation has been a well of constitutional problems because, as one authority has put it,

> "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." Sutherland's Statutes and Statutory Construction § 41.02 (4th ed. 1972).

Retroactive legislation in the patent area presents an especially clear case of unfairness because the government is a party to the patent grant. In addition, patent owners have always relied on the express terms of the patent statute and on constitutionally grounded public policy when they disclose their inventions.

13. To avoid the constitutional difficulties inherent in retroactive legislation, Congress has traditionally been careful to legislate prospectively. Thus, it has limited the effect of new statutes on existing patent rights; the Patent Act of 1952 provides that "any rights or liabilities now existing under such [repealed] section or parts thereof shall not be affected by this repeal." Act of July 19, 1952, § 5, 66 Stat. 815.

14. If Section 202 were merely prospective in its application, applying only to patents issued after enactment, the "taking" problem would be avoided entirely. The rights of property involved here are substantial and the constitutional infirmities significant.