[illegible]

To [illegible] my [illegible] I have [illegible] the [illegible] and [illegible] [illegible], the [illegible] enhancing the competitive position of the competitor, and that [illegible] to improve his competitive position stimulates the competitor to invest in [illegible]. I [illegible] to close by describing in some detail another specific situation that illustrates both the tensions and the blending of our laws as they affect those who innovate.

As reported in the September 7, 1978 issue of the Patent, Trademark & Copyright Journal [591 PTCJ A-1, E-1], the Solicitor General has filed an amicus curiae brief in the Supreme Court in which the United States sides with the inventor in the Quick Point case. There the inventor and the manufacturing-licensor entered into an agreement requiring the licensor to pay either a specified royalty if a patent were granted or a reduced royalty for an indefinite period if no patent issued. No patent issued, and after paying royalties for almost 20 years, the licensor discontinued making payments and sought a declaratory judgment that its agreement with the inventor was unenforceable by virtue of being pre-empted by the federal patent laws or the national policy favoring competition.

In supporting the inventor's claim that the agreement should be enforced, the Government focuses primarily on why such contractual arrangements are consistent with federal competition and patent policies. As to those policies, the brief for the United States re-affirms the theme I would leave with you today:

> The federal patent laws, 35 U.S.C. 101 et seq., encourage invention, foster full disclosure of useful discoveries, and ensure that commercial innovations are available to the public. Kewanee Oil Co. v. Bicron Corp., 415 U.S. 470, 480-481, 484. Federal competition policy, as established principally in the Sherman and Clayton Acts, 26 Stat. 209, 38 Stat. 730, as amended, 15 U.S.C. 1 et seq., also seeks to encourage the development of, and competition in, new products. The patent and antitrust laws, taken together, recognize that a limited period of monopoly will both encourage discoveries and enable inventors to coordinate the employment of resources in research and development; but the employment of the patent monopoly depends on true inventiveness, and in the main "the unrestrained interaction of competitive forces will yield the best allocation of our economic resources, the lowest prices, the highest quality and the greatest material progress." Northern Pacific Ry. v. United States, 356 U.S. 1, 4. [End Text]

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GOVERNMENT REPORT NOTES MORE INNOVATION IN SMALLER FIRMS

At a time when legislation has been proposed that would allow small businesses to obtain patent rights in technology developed with Government funds (see 396 PTCJ A-1, D-1), the Administrator for Federal Procurement Policy has called attention to a Government report which suggests that small firms are much more innovative than large firms.

Testifying September 25th before the House Small Business Subcommittee on Antitrust, Consumers and Employment, Lester A. Fettig, Administrator for Federal Procurement Policy, stressed that the Office of Federal Procurement Policy (an arm of the Office of Management and Budget) is committed to Government utilization of small high-technology businesses. In listing actions reflecting OFPP's commitment, Fettig stated that he has formally issued the "Rabinow Report," which contains recommendations for increasing small firm participation in federal research and development work. Dated February 24, 1977, the report cites findings by economist William K. Scheirer that small firms have a better record of innovation than large firms. In spite of these findings, the report also notes that a "striking disparity appears to exist between the capabilities of small technology-based firms and their utilization by federal agencies."

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A summary of the report recently provided to the House subcommittee includes the following statements:

[Text] Small firms have compiled a striking record of innovation in the private sector:

Firms with less than 1,000 employees accounted for almost 1/2 of major U.S. innovations during 1953-73.

The ratio of innovations to sales is about 1/3 greater in firms with less than 1,000 employees than in firms of over 1,000 employees.

Firms of less than 1,000 employees have a ratio of innovations to R&D employment which is approximately four times greater compared to firms with more than 1,000 employees.

The cost per R&D scientist or engineer is almost twice as great in firms of over 1,000 employees than in firms with less than 1,000 employees. [End Text]

Copies of the Rabinow Report and the Scheirer study (OMB/OFPP/CA-77/1) may be obtained from the Office of Federal Procurement Policy, Office of Management and Budget, Room 9001, 726 Jackson Place, Washington, D.C. 20503. Telephone: (202) 395-3455.

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FDA PROPOSES ABOLITION OF "MAN-IN-THE-PLANT" PRACTICE

Responding to intense pressure from several members of Congress, the Food and Drug Administration has proposed amending its rules to abolish the practice of allowing brand-name drug manufacturers to represent generic drugs as their own by simply maintaining a "man-in-the-plant" of a generic manufacturer.

Concern about the high cost of drugs sparked several congressional inquiries which in turn led to angry denunciations of the "man-in-the-plant" practice. Senator Nelson (D-Wis.) and others did not seem to feel there was any safety hazard resulting from this practice, but they were irked by the substantial mark-up in prices charged for goods produced by generic manufacturers but sold under a brand name. See 354 PTCJ A-15, 392 PTCJ A-20, 396 PTCJ A-14, 397 PTCJ A-14.

FDA Commissioner Donald Kennedy, and Health, Education, and Welfare Secretary Joseph Califano, separately pledged to congressional committees that regulations dealing with the "man-in-the plant" practice would be forthcoming. The proposals now issued reflect Kennedy's conclusion that "the [FDA's] 'man-in-the-plant' policy is no longer appropriate as a basis for identifying a firm as the manufacturer of a drug." Noting that the public "may be mislead" by the current policy, FDA says a consumer "is entitled to know when a company is distributing a drug or drug product it did not manufacture."

The proposed rules are designed to state clearly who may be identified as the "manufacturer" of a drug. Thus, a "manufacturer" will be defined as one who performs all of the significant operations which apply to the drug. If manufacturing operations are performed by two or more persons, each may be identified as a joint manufacturer.

Three conditions would have to be met before a company could qualify as a manufacturer. The conditions are that the manufacturing operations: (1) be performed by individuals, a majority of whom are permanent full-time employees of the company and are subject to the company's direct supervision through the personnel of the operation, (2) be performed in premises that are owned or leased by the company and are not leased to another company's operation, and (3) be performed [illegible]