PATENT RESTORATION ACT

I. BACKGROUND

H.R. 1937, the Patent Term Restoration Act, is designed to correct a current inequity in the patent law. The patent law gives an inventor 17 years of market exclusivity for a patented invention. However, for certain products, such as chemicals and drugs, the 17-year patent term has been unintentionally eroded by Federal premarket testing and review requirements. For example, under the Federal Insecticide, Fungicide and Rodenticide Act, a pesticide may not be marketed until it has been thoroughly tested for safety and approved by EPA. According to EPA, this process may take as long as 5-7 years, during which time the 17-year clock on the patent term is ticking away. Drugs face similar regulatory requirements, and the average effective patent life for those approved in 1981 was only 6.8 years.

The patent has traditionally provided a major incentive for costly, risky R&D. Without it, many important advancements in the medical, agricultural and other fields probably would not have occurred or been economically feasible. H.R. 1937 renews this incentive by restoring to the patent term that period lost to regulatory testing and review, but not to exceed seven years. The bill does not apply to patented products which have completed the regulatory review process.

H.R. 1937 has 90 cosponsors. A clean bill was favorably reported by the Subcommittee on Courts, Civil Liberties and the Administration of Justice on March 25, 1982. Similar legislation passed the Senate by voice vote on July 9, 1981.

II. SUBCOMMITTEE AMENDMENTS

During Subcommittee markup, six amendments were adopted in bloc. Unfortunately, two of these amendments seriously undermine the bill's objective of stimulating innovation in the United States during the immediate years ahead.

A. Inventions Not Yet Through Regulatory Review

The Subcommittee adopted an amendment denying any patent restoration relief to any invention already under patent, even though all or part of the regulatory testing and review period has not yet been completed, and indeed, may not have begun. The amendment defers needed patent relief and thereby eliminates most of the bill's stimulus effect upon innovation during the immediate years ahead. Now no patent restoration will occur until 17 years after enactment, i.e., 1999. This is in contrast to H.R. 1937 as introduced which measured the regulatory review period (and thus the amount of patent restoration) for such inventions from the date of the bill's enactment. It was prospective only since it limited the term of restoration for any invention receiving approval/review after that date to the

duration of subsequent premarket review. It denied patent restoration for any invention receiving regulatory approval/ review prior to the enactment date.

The amendment adopted by the Subcommittee denies all restoration relief to an invention whose patent issues as little as one day prior to the date of enactment, but allows full restoration, up to seven years, to an invention whose patent is issued one day later. In both cases, the inventions must undergo regulatory review. This arbitrary cutoff is inequitable and much less desirable to the phased-in, prospective approach of the bill as introduced.

Issuance of a patent is only a first step in the research and development process. Investment decisions must be made at each step in the process as to the economic feasibility of initiating or continuing the costly and time consuming testing and regulatory review process. The length of the patent term is a major determinant in these decisions. The continued erosion of the effective patent life on these inventions will be a major disincentive to continue the investment required to bring them to market.

Finally, the amendment is also inconsistent with action taken by this Committee respecting copyrights. In the 1976 amendments to the copyright law, the term of existing copyrights was lengthened by 19 years in order to assure copyright holders the fair economic benefits of their work. Similarly, existing patentees whose products have yet to begin or complete regulatory testing and review deserve the fair economic benefits of their work.

B. Inventions Subject To Less Than One Year Of Regulatory Review

The Subcommittee adopted an amendment denying patent term restoration to products subject to less than one year of regulatory review. This amendment has the effect of denying patent term restoration to the vast majority of chemical products subject to regulation by EPA under the Toxic Substances Control Act (TSCA).

Except in unusual cases, EPA review of chemical substances under TSCA will be less than one year in duration (i.e., 90-180 days). Pursuant to Section 5(a) and (b) of TSCA, parties seeking to manufacture a new chemical substance must submit a premanufacture notice (PMN) with supporting data to EPA at least 90 days prior to the manufacture of such substance. Within this 90-day period, EPA reviews the submission and for "good cause" may extend its review for an additional 90 days. Following completion of this review period, the submitter may begin to manufacture the substance in the absence of an EPA order or court injunction prohibiting or limiting its manufacture. Should an EPA order or court injunction issue, commercialization of the new

chemical substance may be held in abeyance until either the EPA order or court injunction is rescinded.

If one accepts the basic premise of patent term restoration, i.e., products subject to federal premarket review should not lose valuable patent life because of these review requirements, it should not make any difference whether the regulatory review period is six months or six years. It seems arbitrary to deny patent term restoration to products merely because they have incurred a regulatory review period of 364 days rather than 365 days or more. The patent life lost in either case will be significant to the innovator.

III. Recommended Action

It is urged that both of these provisions adopted by the Subcommittee be deleted from the bill when the full Judiciary Committee considers it.