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REMARKS:

by Mr. Sawyer

PATENT RESTORATION ACT

HON. HAROLD S. SAWYER
OF MICHIGAN
IN THE HOUSE OF REPRESENTATIVES

Thursday, February 19, 1981

● Mr. SAWYER. Mr. Speaker, I have today joined my distinguished colleague, Mr. KASTENMEIER, chairman of the Judiciary Subcommittee on Courts, Civil Liberties, and the Administration of Justice on which I serve, in introducing the Patent Restoration Act of 1981. This bill is designed to restore equity and fairness to the American patent system and to help reverse the clearly evident decline in American technological innovation.

Specifically, this legislation would permit the restoration of patent life lost due to federally mandated premarket testing and regulatory review. The maximum restoration period allowed would be 7 years. Moreover, the patent life thus restored would apply only to the specific use for which regulatory review was required and not to the range of other products or uses which might otherwise derive from the patent in question.

As you all know, under current law, an innovator is awarded a patent on a new product or discovery that extends for a period of 17 years. This period of protection is designed to encourage the innovation process and has worked exceedingly well throughout most of our history. For some products, however, a considerable portion of patent life is eaten up by extensive premarket testing and regulatory review imposed by the Federal Government. Take the pharmaceutical industry, for example. It is now estimated to take some 7 to 10 years to move a new drug product through testing and development to final marketing approval. Throughout this process, the life of the patent is ticking away and is frequently reduced by one-half. The result has been a clearly discernable decline in therapeutic drug innovation in the United States. Chemical companies, medical device manufacturers, and agricultural chemical producers face a similar dilemma.

The Patent Restoration Act would eliminate this incongruous situation in which one arm of Government awards a 17-year patent to stimulate innovation and another arm of Government takes one-half of it away. It would in no way effect our strong commitment to the public that only safe products are placed on the market. Yet it will alleviate the inadvertent effect that such premarket testing and regulatory review requirements have had on the patent system to the detriment of innovation.

The legislation takes a simple and flexible approach to the problem. The relevant regulatory review periods for which patent restoration is available are clearly defined and easily measured. Hence no new bureaucracy will be needed to administer the act. In addition, the bill provides for the restoration of patent life only to the extent that it has been reduced by regulatory review requirement. If and when this regulatory period is reduced by whatever means, the available restoration period would be correspondingly less.

Enactment of this legislation could be particularly beneficial to our small innovative companies that have been most affected by the time-consuming and costly nature of the regulatory process and least able to afford the resulting loss of patent protection. I also believe it will bring significant benefits to our consumers as more resources are attracted back into the innovation process and new and better products are made available to the public.

One of the greatest challenges before the 97th Congress is to find ways to revitalize the American economy. Restoration or the incentive to innovate and create should become one of our principal objectives in this effort. The Patent Restoration Act of 1981 is a simple, equitable, and cost-effective means to achieve this goal and should be a priority on our legislative agenda in the 97th Congress.●