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Introduced by Mr. Kastenmeier

PATENT TERM AND REGULATORY DELAY

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OF WISCONSIN.

IN THE HOUSE OF REPRESENTATIVES

Wednesday, February 18, 1981

● Mr. KASTENMEIER. Mr. Speaker, on December 12, last year, the President signed into law the most far-reaching amendments to the patent law in nearly 30 years.

These amendments were designed to modernize the patent system so as to promote commitment of the risk capital necessary to develop the advanced technology which is central to our Nation's economic well-being.

Patents and the patent system play an important role in the process of investment in new technology in several ways.

First, the grant of a patent assures to an inventor and investor a 17-year period during which the enormous costs of development may be amortized.

Second, the patent, although creating exclusive rights in an invention, is also a publicly disseminated document, publicized widely and available to competing inventors. This encourages the rapid dissemination of information about new technology which in turn spurs additional inventions.

Public Law 96-517, the bill signed last year, addressed three critical problem areas in the patent system: reexamination, Government patent policy, and patent fees.

However, during the course of hearings and markup on that legislation other issues arose, including the administrative structure of the patent system and the question of loss of effective patent life due to premarket regulatory delay. On the question of loss of effective patent term, members of the subcommittee, in particular my distinguished colleague from Michigan, Mr. Sawyer, graciously withdrew proposed amendments with the understanding that the question of restoring patent term lost due to regulatory delay would be considered separately in the 97th Congress.

It is with that understanding in mind that I am today introducing the Patent Term Restoration Act of 1981.

Proponents of patent life restoration argue that in many cases, especially in the pharmaceutical and chemical industries, the extensive and necessary premarket clearance procedures of agencies such as the FDA and EPA, reduce effective patent life so drastically as to make it increasingly difficult to attract the risk capital necessary to developing useful new products.

It is argued that the negative impact of lost patent life upon innovation is readily apparent in the pharmeceutical field. When a researcher uncovers a promising new chemical compound, he files for a patent. That patent usually is granted within 2 years, and the 17-year period of protection commences. New compounds are rarely marketable at this point, however, it now takes an average of 7 to 10 years and about $70 million to complete the testing period and the Food and Drug Administration's approval procedures before medicines are made available to the general public. The effective patent life for such products is, therefore, in the neighborhood of 7 to 10 years.

As a result of declining patent lives and the concomitant increase in time and expenses required to develop and market new therapies, many in the pharmaceutical industry believe that the flow of new medicines to the public has diminished. From 1955 through 1962, an average of 46 new drugs were introduced annually in the United States; today that average is only 17 a year, a decline of 63 percent. Late in the last Congress, I introduced for comment H.R. 7952, embodying the patent term restoration concept. My purpose in introducing the bill was to generate study, comment, and criticism on the issue. That process has now begun and is continuing. For example, we expect that prelimiary information on this issue and other patent related matters soon will be forthcoming in connection with a study by the Office of Technology Assessment.

It is my intention that hearings on the bill will elicit many more comments, information, and criticism.

The legislation I am introducing today is very similar to the bill I introduced last Congress with one exception. Last year the legislation covered medical devices, drugs, and other chemical products such as pesticides and industrial chemicals. This year a new provision has been added at section 155(c)(4)(D) to cover other products subject to Federal premarketing review or notification requirements, because a number of people have expressed the concern that Federal premarketing requirements have eroded the patent life in less visible areas as well. Although I take no position on its merits. I have included the additional provision in the bill in order to draw attention to the issue when we have our hearings. Proponents of the broader coverage will be invited to make their case during our hearings, so that members of the subcommittee can make an informed decision on the issue.

I also urge groups representing consumers and other interested parties to plan on presenting their views during our hearings. Such broad participation will insure that there is a full and fair examination of the need for the legislation.●