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Action:

Remarks by Mr. D'Amato

S. 1306—THE PATENT TERM RESTORATION ACT OF 1983

● Mr. D'AMATO. Mr. President, I rise today in support of S. 1306, the Patent Term Restoration Act of 1983. I commend Senator MATHIAS, the distinguished chairman of the Subcommittee on Patents, Copyrights and Trademarks, for authoring and introducing this measure. Hearings on this important initiative were held on June 22 and July 19, 1983.

The predecessor of S. 1306 in the 97th Congress passed the Senate by voice vote on July 9, 1981. It is my hope that S. 1306 will pass both Houses and become law during the 98th Congress.

In accordance with article I, section 8, of the Constitution, the Congress has enacted laws to promote the development of new products by providing patent holders with 17 years of protection for their inventions and discoveries. Our inventors, in turn, have provided the American people with the health and other social benefits of the world's leading pharmaceutical and agricultural chemical discoveries.

We have also enacted, over the years, a series of laws to protect the public and the environment from harmful products. These laws require extensive and time-consuming tests before products affecting the public health and environment may be introduced into the marketplace. However, while such premarketing review is pending, the clock continues to run on the patent involved. In the case of pharmaceuticals, for example, the average review can last for well over half the life of a patent. Medicines approved during 1981 lost an average of 10.2 years of their statutory 17-year patent lives before their first sales. In other words, new medicines had an effective patent life of 6.8, rather than 17, years. In 1979, they had 9.5 years remaining after their regulatory clearances. During the period 1962-66, there were 14.9 years of patent life remaining after Food and Drug Administration approval. Thus, it is apparent that the period of useful patent life is growing continually shorter.

It is important to note that S. 1306 does not dilute the strength of the premarket review process. It merely restores the patent life that may be consumed during that process. Under its terms, the 17-year clock would start to run only after a new product obtains marketing approval, rather than when the patent application is filed.

There are three reasons to support S. 1306. The first of these is that is will guarantee fairness to all patent holders. No longer will some inventors be penalized excessively for the necessary, but increasingly time-consuming, premarket testing we require for certain drugs and chemicals.

The second reason is that the bill will promote technological innovation. A growing number of drugs and chemcials are being discovered or licensed today in foreign countries, where the patent rules are more favorable. In 1981, only 7 of 20 new chemical entities were United States originated.

The third reason is that S. 1306 will encourage lower prices for new drugs, chemicals, and other products by stimulating their development. The resultant lower prices for new drugs and medicines will be of special benefit to our Nation's elderly, who are, per capita, the largest consumers of these products.

To assist American scientific development and maintain our lead in the face of rising costs and growing foreign competition, to promote fairness, and to preserve the original intent of the patent system, namely, the societal benefits that flow from the progress of science, I urge my colleagues to support S. 1306.