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S. 255	April 29, 1981	S 4170-71

Remarks by Mr. East.

S. 255, THE PATENT TERM RESTORATION ACT OF 1981

● Mr. EAST. Mr. President, I am today cosponsoring S. 255, the Patent Term Restoration Act of 1981. I am pleased to note that this bill already has some 25 sponsors in the Senate and that it will be the subject of hearings tomorrow before the Committee on the Judiciary.

Under the authority of article I, section 8 of the U.S. Constitution to "promote the Progress of Science and useful Arts," Congress enacted laws to encourage the research and development of new products by providing the holders of all patents with 17 years of protection for their discoveries. However, some products, such as drugs and chemicals, require a lengthy approval process by the Federal Government to demonstrate safety and effectiveness before they can be marketed. Thus, patented products undergoing a review and approval process by a government agency are being kept out of the commercial market and are being denied part of their congressionally guaranteed 17 years of patented life protection.

As an example, it now takes, on average, 7 to 10 years to develop and test a pharmaceutical product. Thus, it is not unusual for a drug product to lose up to one-half of its patent life before it is approved for marketing by the Food and Drug Administration. Similarly, the Environmental Protection Agency has estimated that the patent life for chemical products has been reduced to about 12 years.

To correct this inequity, the Patent Term Restoration Act simply would restore the patent life that has been consumed during a particular product's review and approval process. Specifically, the bill directs that a regulatory review period be calculated for each product that undergoes Federal preclearance procedures and that an equal amount of time be restored to that product's patent, with a maximum restoration period of 7 years.

Passage of the bill would restore fundamental fairness by fulfilling the intent of Congress that all inventions be accorded equal and adequate protection. The bill would also help stimulate investment in the research and development of products such as drugs and chemicals that require lengthy governmental approval. Increasing such incentives will help stimulate the flow of new and improved products to the public. In the health area, for example, the bill will encourage the development of better medicines which often obviate the need for more costly forms of therapy, such as surgery or hospitalization.

The bill that I am supporting would in no way affect our strong commitment to the public that only safe products are placed on the market. Yet it will alleviate the inadvertent effect that premarket testing and regulatory review requirements have had on the patent system to the detriment of innovation.

One of the greatest challenges we face in the 97th Congress is to find ways to revitalize the American economy. Restoration of the incentive to innovate and create should be one of our principal objectives in this revitalization effort. S. 255 is a simple, equitable, and cost-effective means to achieve this goal and should be a priority item on our legislative agenda. It is therefore my hope that the Committee on the Judiciary and the full Senate will promptly approve this bill.●