

104<sup>TH</sup> CONGRESS  
1<sup>ST</sup> SESSION

# H. R. 2467

To grant certain patent rights for certain nonsteroidal anti-inflammatory drugs for a 2-year period.

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## IN THE HOUSE OF REPRESENTATIVES

OCTOBER 11, 1995

Mr. HASTERT (for himself, Mr. PORTER, Mrs. COLLINS of Illinois, Mr. RUSH, and Mr. NORWOOD) introduced the following bill; which was referred to the Committee on the Judiciary, and in addition to the Committee on Commerce, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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## A BILL

To grant certain patent rights for certain nonsteroidal anti-inflammatory drugs for a 2-year period.

1       *Be it enacted by the Senate and House of Representa-*  
2       *tives of the United States of America in Congress assembled,*

3       **SECTION 1. GRANTING CERTAIN PATENT RIGHTS RELAT-**  
4       **ING TO CERTAIN DRUGS.**

5       (a) IN GENERAL.—Any owner on the date of enact-  
6       ment of this Act of the right to market a nonsteroidal anti-  
7       inflammatory drug that—

8               (1) contains a previously patented active agent;

1           (2) has been reviewed by the Federal Food and  
2       Drug Administration for a period of more than 120  
3       months as a new drug application; and

4           (3) was approved as safe and effective by the  
5       Federal Food and Drug Administration on October  
6       29, 1992,

7       shall be entitled, for the 2-year period beginning on Octo-  
8       ber 29, 1997, to exclude others from making, using, offer-  
9       ing for sale, selling, or importing into the United States  
10      such active agent, in accordance with section 154(a)(1)  
11      of title 35, United States Code.

12      (b) INFRINGEMENT.—Section 271 of title 35, United  
13      States Code shall apply to the infringement of the entitle-  
14      ment provided under subsection (a). No application de-  
15      scribed in section 271(e)(2)(A) of title 35, United States  
16      Code, regardless of purpose, may be submitted prior to  
17      the expiration of the entitlement provided under sub-  
18      section (a).

19      (c) NOTIFICATION.—Not later than 30 days after the  
20      date of the enactment of this Act, any owner granted an  
21      entitlement under subsection (a) shall notify the Commis-  
22      sioner of Patents and Trademarks and the Secretary for  
23      Health and Human Services of such entitlement. Not later  
24      than 7 days after the receipt of such notice, the Commis-

- 1 sioner and the Secretary shall publish an appropriate no-
- 2 tice of the receipt of such notice.

