

104TH CONGRESS  
1ST SESSION

# S. 1496

To grant certain patent rights for certain non-steroidal anti-inflammatory drugs for a two-year period.

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## IN THE SENATE OF THE UNITED STATES

DECEMBER 21, 1995

Mr. SIMON (for himself, Mr. HATCH, Mr. BOND, and Mr. ASHCROFT) introduced the following bill; which was read twice and referred to the Committee on the Judiciary

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## A BILL

To grant certain patent rights for certain non-steroidal anti-inflammatory drugs for a two-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. FINDINGS.**

4 Congress finds the following:

5 (1) The length of the regulatory review process  
6 required for approval of new drugs by the Federal  
7 Food and Drug Administration (FDA) has varied  
8 greatly.

9 (2) For virtually all new drugs, this FDA re-  
10 view takes place after the drug has been patented,

1       thereby decreasing the protections that are provided  
2       under law as an incentive to those who invest in de-  
3       veloping new medications, including the 17- or 20-  
4       year prohibition on the use of a patented medication  
5       by others.

6               (3) In instances of inordinately long periods of  
7       review by the FDA, Congress has provided for the  
8       restoration of all or a portion of the period  
9       consumed by the review.

10              (4) In 1984, Congress enacted the Drug Price  
11       Competition and Patent Term Restoration (Hatch-  
12       Waxman) Act, which was designed in part to provide  
13       for the partial and limited restoration of protections  
14       lost when drugs are subject to long FDA review.

15              (5) Congress has previously recognized, through  
16       the passage of legislation, that the added protections  
17       provided for by the Hatch-Waxman Act may not  
18       adequately address all instances of regulatory delay.

19              (6) In 1992, the FDA granted marketing ap-  
20       proval for the active agent in the non-steroidal anti-  
21       inflammatory drug (NSAID) oxaprozin. The inves-  
22       tigational new drug application for oxaprozin had  
23       been filed with the FDA in 1971 and the new drug  
24       application had been filed with the agency in 1982.  
25       Because the FDA approval process lasted 21 years,

1 the entire 17-year patent life of oxaprozin had ex-  
2 pired by the time the FDA approved the drug.  
3 Oxaprozin was approved by the FDA on the basis of  
4 the initial studies submitted with the new drug ap-  
5 plication filed in 1982.

6 (7) At the request of the Committees of the Ju-  
7 diciary in each House of Congress, the General Ac-  
8 counting Office (GAO), during 1992, investigated  
9 the FDA review of two other drugs that, like  
10 oxaprozin, were NSAIDs. As part of the reviews, the  
11 GAO essentially found that, with respect to the en-  
12 tire class of NSAIDs, there was a two-year period of  
13 inactivity at the FDA from May 1984 through May  
14 1986. Based in significant part upon this GAO find-  
15 ing, both Houses of Congress subsequently passed  
16 legislation to provide additional market protection to  
17 certain NSAIDs harmed by this inactivity.

18 (8) No class of drugs other than the NSAID  
19 class, of which oxaprozin is a part, has been found  
20 by the GAO, the relevant Committees and both  
21 Houses in previous Congresses, to have incurred  
22 such class-wide delays.

23 (9) Since the enactment of the Hatch-Waxman  
24 Act, no drug other than oxaprozin has had its entire  
25 patent life consumed by FDA review.

1           (10) In order to redress the unique harm done  
2           to oxaprozin, the further restoration of rights for  
3           oxaprozin as provided in this bill should be enacted  
4           as promptly as possible.

5 **SEC. 2. GRANTING CERTAIN PATENT RIGHTS RELATING TO**  
6 **CERTAIN DRUGS.**

7           (a) IN GENERAL.—Any owner on the date of enact-  
8           ment of this Act of the right to market a non-steroidal  
9           anti-inflammatory drug that—

10           (1) contains a previously patented active agent;

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

14           (3) was approved as safe and effective by the  
15           Federal Food and Drug Administration on October  
16           29, 1992,

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

22           (b) INFRINGEMENT.—Section 271 of title 35, United  
23 States Code, shall apply to the infringement of the entitle-  
24 ment provided under subsection (a). No application de-  
25 scribed in section 271(e)(2)(A), regardless of purpose,

1 may be submitted prior to the expiration of the entitle-  
2 ment provided under subsection (a).

3 (c) NOTIFICATION.—No later than 30 days after the  
4 date of the enactment of this Act, any owner granted an  
5 entitlement under subsection (a) shall notify the Commis-  
6 sioner of Patents and Trademarks and the Secretary for  
7 Health and Human Services of such entitlement. No later  
8 than 7 days after receipt of such notice, the Commissioner  
9 and the Secretary shall publish appropriate notice thereof.

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