

103<sup>D</sup> CONGRESS  
1<sup>ST</sup> SESSION

# H. R. 3379

To amend section 156 of title 35, United States Code, to provide for the interim extension of patents subject to that section.

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IN THE HOUSE OF REPRESENTATIVES

OCTOBER 27, 1993

Mr. HUGHES introduced the following bill; which was referred to the Committee on the Judiciary

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## A BILL

To amend section 156 of title 35, United States Code, to provide for the interim extension of patents subject to that section.

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. INTERIM PATENT EXTENSIONS.**

4       Section 156(d) of title 35, United States Code, is  
5 amended—

6             (1) in the second sentence of paragraph (1) by  
7       striking “Such” and inserting “Except as provided  
8       in paragraph (5), such”; and

9             (2) by adding at the end the following new  
10       paragraph:

1       “(5)(A) If the owner of record of the patent or its  
2 agent reasonably expects that the applicable regulatory re-  
3 view period described in paragraph (1)(B)(ii), (2)(B)(ii),  
4 (3)(B)(ii), (4)(B)(ii), or (5)(B)(ii) of subsection (g) that  
5 began for a product that is the subject of such patent may  
6 extend beyond the expiration of the patent term in effect,  
7 the owner or its agent may submit an application to the  
8 Commissioner for an interim extension during the period  
9 beginning 6 months, and ending 30 days, before such term  
10 is due to expire. The application shall contain—

11               “(i) the identity of the product subject to regu-  
12 latory review and the Federal statute under which  
13 such review is occurring;

14               “(ii) the identity of the patent for which interim  
15 extension is being sought and the identity of each  
16 claim of such patent which claims the product under  
17 regulatory review or a method of using or manufac-  
18 turing the product;

19               “(iii) information to enable the Commissioner  
20 to determine under subsection (a)(1), (2), and (3)  
21 the eligibility of a patent for extension;

22               “(iv) a brief description of the activities under-  
23 taken by the applicant during the applicable regu-  
24 latory review period to date with respect to the prod-

1       uct under review and the significant dates applicable  
2       to such activities; and

3               “(v) such patent or other information as the  
4       Commissioner may require.

5       “(B) If the Commissioner determines that, except for  
6       permission to market or use the product commercially, the  
7       patent would be eligible for an extension of the patent  
8       term under this section, the Commissioner shall publish  
9       in the Federal Register a notice of such determination,  
10      including the identity of the product under regulatory re-  
11      view, and shall issue to the applicant a certificate of in-  
12      terim extension for a period of not more than 1 year.

13      “(C) The owner of record of a patent, or its agent,  
14      for which an interim extension has been granted under  
15      subparagraph (B), may apply for not more than 4 subse-  
16      quent interim extensions under this paragraph. Each such  
17      subsequent application shall be made during the period be-  
18      ginning 60 days before, and ending 30 days before, the  
19      expiration of the preceding interim extension.

20      “(D) Each certificate of interim extension under this  
21      paragraph shall be recorded in the official file of the pat-  
22      ent and shall be considered part of the original patent.

23      “(E) Any interim extension granted under this para-  
24      graph shall terminate at the end of the 60-day period be-  
25      ginning on the date on which the product involved receives

1 permission for commercial marketing or use, except that,  
2 if within that 60-day period the applicant notifies the  
3 Commissioner of such permission and submits any addi-  
4 tional information under paragraph (1) of this subsection  
5 not previously contained in the application for interim ex-  
6 tension, the patent shall be further extended in accordance  
7 with the provisions of this section, not to exceed 5 years  
8 from the date of expiration of the original patent term.

9 “(F) The rights derived from any patent the term  
10 of which is extended under this paragraph shall, during  
11 the period of interim extension—

12 “(i) in the case of a patent which claims a  
13 product, be limited to any use then under regulatory  
14 review;

15 “(ii) in the case of a patent which claims a  
16 method of using a product, be limited to any use  
17 claimed by the patent then under regulatory review;  
18 and

19 “(iii) in the case of a patent which claims a  
20 method of manufacturing a product, be limited to  
21 the method of manufacturing as used to make the  
22 product then under regulatory review.”.

23 **SEC. 2. CONFORMING AMENDMENTS.**

24 Section 156 of title 35, United States Code, is  
25 amended—

1 (1) in subsection (a)—

2 (A) in paragraph (1) by striking “(d)” and  
3 inserting “(d)(1)”; and

4 (B) in paragraph (3) by striking “sub-  
5 section (d)” and inserting “paragraphs (1)  
6 through (4) of subsection (d)”;

7 (2) in subsection (b) by striking “The rights”  
8 and inserting “Except as provided in subsection  
9 (d)(5)(F), the rights”; and

10 (3) in subsection (e)—

11 (A) in paragraph (1) by striking “sub-  
12 section (d)” and inserting “paragraphs (1)  
13 through (4) of subsection (d)”;

14 (B) in paragraph (2) by striking “(d)” and  
15 inserting “(d)(1)”.

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