

103D CONGRESS  
1ST SESSION

# H. R. 760

To amend title 35, United States Code, with respect to patents on certain processes.

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IN THE HOUSE OF REPRESENTATIVES

FEBRUARY 3, 1993

Mr. BOUCHER (for himself, Mr. MOORHEAD, Mr. COBLE, Mr. KOPETSKI, Mr. McDERMOTT, Mr. DICKS, Mr. BLILEY, Mr. GALLEGLY, and Mr. MCCOLLUM) introduced the following bill; which was referred to the Committee on the Judiciary

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## A BILL

To amend title 35, United States Code, with respect to patents on certain processes.

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

3 **TITLE I—BIOTECHNOLOGICAL**  
4 **PROCESS PATENTS**

5 **SEC. 101. CONDITIONS FOR PATENTABILITY; NONOBVIOUS**  
6 **SUBJECT MATTER.**

7 Section 103 of title 35, United States Code, is  
8 amended—

1           (1) in the first unnumbered paragraph by in-  
2       serting “(a)” before “A patent”;

3           (2) in the second unnumbered paragraph by in-  
4       serting “(b)” before “Subject matter”; and

5           (3) by adding at the end thereof the following  
6       new subsections:

7       “(c) Notwithstanding any other provision of this sec-  
8       tion, a claimed process of making or using a machine,  
9       manufacture, or composition of matter is not obvious  
10      under this section if—

11           “(1) the machine, manufacture, or composition  
12       of matter is novel under section 102 of this title and  
13       nonobvious under this section;

14           “(2) the claimed process is a biotechnological  
15       process as defined in subsection (d); and

16           “(3)(A) the machine, manufacture, or composi-  
17       tion of matter, and the claimed process invention at  
18       the time it was made, were owned by the same per-  
19       son or subject to an obligation of assignment to the  
20       same person; and

21           “(B) claims to the process and to the machine,  
22       manufacture, or composition of matter—

23           “(i) are entitled to the same effective filing  
24       date; and

1           “(ii) appear in the same patent applica-  
2           tion, different patent applications, or patent  
3           which is owned by the same person and which  
4           expires or is set to expire on the same date.

5           “(d) For purposes of this section, the term  
6           ‘biotechnological process’ means any method of making or  
7           using living organisms, or parts thereof, for the purpose  
8           of making or modifying products. Such term includes re-  
9           combinant DNA, recombinant RNA, cell fusion including  
10          hybridoma techniques, and other processes involving site  
11          specific manipulation of genetic material.”.

12   **SEC. 102. NO PRESUMPTION OF INVALIDITY.**

13          The first unnumbered paragraph of section 282 of  
14          title 35, United States Code, is amended by inserting after  
15          the second sentence “A claim issued under the provisions  
16          of section 103(c) of this title on a process of making or  
17          using a machine, manufacture, or composition of matter  
18          shall not be held invalid under section 103 of this title  
19          solely because the machine, manufacture, or composition  
20          of matter is determined to lack novelty under section 102  
21          of this title or to be obvious under section 103 of this  
22          title.”.

23   **SEC. 103. EFFECTIVE DATE.**

24          The amendments made by this title shall apply to all  
25          United States patents granted on or after the date of the

1 enactment of this Act and to all applications for United  
2 States patents pending on or filed after such date of enact-  
3 ment, including any application for the reissuance of a  
4 patent.

## 5 **TITLE II—BIOTECHNOLOGICAL** 6 **MATERIAL PATENTS**

### 7 **SEC. 201. INFRINGEMENT BY IMPORTATION, SALE OR USE.**

8 (a) INFRINGEMENT.—Section 271 of title 35, United  
9 States Code, is amended by adding at the end the follow-  
10 ing new subsection:

11 “(h) Whoever without authority imports into the  
12 United States or sells or uses within the United States  
13 a product which is made by using a biotechnological mate-  
14 rial (as defined under section 154(b)) which is patented  
15 in the United States shall be liable as an infringer if the  
16 importation, sale, or use of the product occurs during the  
17 term of such patent.”.

18 (b) CONTENTS AND TERM PATENT.—Section 154 of  
19 title 35, United States Code, is amended—

20 (1) by inserting “(a)” before “Every”;

21 (2) by striking out “in this title,” and inserting  
22 in lieu thereof “in this title (1)”;

23 (3) by striking out “and, if the invention” and  
24 inserting “(2) if the invention”;

1           (4) by inserting after “products made by that  
2           process,” the following: “and (3) if the invention is  
3           a biotechnological material used in making a prod-  
4           uct, of the right to exclude others from using or sell-  
5           ing throughout the United States, or importing into  
6           the United States the product made or using such  
7           biotechnological material,”; and

8           (5) by adding at the end thereof the following:  
9           “(b) For purposes of this section, the term  
10          ‘biotechnological material’ is defined as any material (in-  
11          cluding a host cell, DNA sequence, or vector) that is used  
12          in a biotechnological process as defined under section  
13          103(d).”.

14          (c) EFFECTIVE DATE.—

15           (1) IN GENERAL.—The amendment made by  
16          this section shall take effect six months after the  
17          date of enactment of this Act and, subject to para-  
18          graph (2), shall apply only with respect to products  
19          made or imported after the effective date of the  
20          amendments made by this section.

21           (2) EXCEPTIONS.—The amendments made by  
22          this section shall not abridge or affect the right of  
23          any person, or any successor to the business of such  
24          person—

1           (A) to continue to use, sell, or import  
2           products in substantial and continuous sale or  
3           use by such person in the United States on the  
4           date of enactment of this Act; or

5           (B) to continue to use, sell, or import  
6           products for which substantial preparation by  
7           such person for such sale or use was made be-  
8           fore such date, to the extent equitable for the  
9           protection of commercial investment made or  
10          business commenced in the United States be-  
11          fore such date.

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