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to Patents on Biotechnological Processes Pub. L.  
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# Calendar No. 191

104TH CONGRESS  
1ST SESSION

# S. 1111

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

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## IN THE SENATE OF THE UNITED STATES

AUGUST 2 (legislative day, JULY 10), 1995

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

SEPTEMBER 18 (legislative day, SEPTEMBER 5), 1995

Reported by Mr. HATCH, without amendment

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## A BILL

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

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. BIOTECHNOLOGICAL PROCESS PATENTS; CON-**  
4 **DITIONS FOR PATENTABILITY; NONOBVIOUS**  
5 **SUBJECT MATTER.**

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

1           (1) by designating the first paragraph as sub-  
2           section (a);

3           (2) by designating the second paragraph as  
4           subsection (c); and

5           (3) by inserting after the first paragraph the  
6           following:

7           “(b)(1) Notwithstanding subsection (a), and upon  
8           timely election by the applicant for patent to proceed  
9           under this subsection, a biotechnological process using or  
10          resulting in a composition of matter that is novel under  
11          section 102 and nonobvious under subsection (a) of this  
12          section shall be considered nonobvious if—

13           “(A) claims to the process and the composition  
14          of matter are contained in either the same applica-  
15          tion for patent or in separate applications having the  
16          same effective filing date; and

17           “(B) the composition of matter, and the process  
18          at the time it was invented, were owned by the same  
19          person or subject to an obligation of assignment to  
20          the same person.

21          “(2) A patent issued on a process under paragraph  
22          (1)—

23           “(A) shall also contain the claims to the com-  
24          position of matter used in or made by that process,  
25          or

1           “(B) shall, if such composition of matter is  
2           claimed in another patent, be set to expire on the  
3           same date as such other patent, notwithstanding  
4           section 154.

5           “(3) For purposes of paragraph (1), the term  
6           ‘biotechnological process’ means—

7           “(A) a process of genetically altering or other-  
8           wise inducing a single- or multi-celled organism to—

9                   “(i) express an exogenous nucleotide se-  
10                  quence,

11                   “(ii) inhibit, eliminate, augment, or alter  
12                  expression of an endogenous nucleotide se-  
13                  quence, or

14                   “(iii) express a specific physiological char-  
15                  acteristic not naturally associated with said or-  
16                  ganism;

17           “(B) cell fusion procedures yielding a cell line  
18           that expresses a specific protein, such as a  
19           monoclonal antibody; and

20           “(C) a method of using a product produced by  
21           a process defined by (A) or (B), or a combination  
22           of (A) and (B).”.

23 **SEC. 2. PRESUMPTION OF VALIDITY; DEFENSES.**

24           Section 282 of title 35, United States Code, is  
25           amended by inserting after the second sentence of the first

1 paragraph the following: “Notwithstanding the preceding  
2 sentence, if a claim to a composition of matter is held in-  
3 valid and that claim was the basis of a determination of  
4 nonobviousness under section 103(b)(1), the process shall  
5 no longer be considered nonobvious solely on the basis of  
6 section 103(b)(1).”.

7 **SEC. 3. EFFECTIVE DATE.**

8       The amendments made by section 1 shall apply to  
9 any application for patent filed on or after the date of  
10 enactment of this Act and to any application for patent  
11 pending on such date of enactment, including (in either  
12 case) an application for the reissuance of a patent.



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