

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

S. 1111

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AN ACT

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,*

1 **SECTION 1. BIOTECHNOLOGICAL PROCESS PATENTS; CON-**  
2 **DITIONS FOR PATENTABILITY; NONOBVIOUS**  
3 **SUBJECT MATTER.**

4 Section 103 of title 35, United States Code, is  
5 amended—

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

8 (2) by designating the second paragraph as  
9 subsection (c); and

10 (3) by inserting after the first paragraph the  
11 following:

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

18 “(A) claims to the process and the composition  
19 of matter are contained in either the same applica-  
20 tion for patent or in separate applications having the  
21 same effective filing date; and

22 “(B) the composition of matter, and the process  
23 at the time it was invented, were owned by the same  
24 person or subject to an obligation of assignment to  
25 the same person.

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

3               “(A) shall also contain the claims to the com-  
4 position of matter used in or made by that process,  
5 or

6               “(B) shall, if such composition of matter is  
7 claimed in another patent, be set to expire on the  
8 same date as such other patent, notwithstanding  
9 section 154.

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

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

14                       “(i) express an exogenous nucleotide se-  
15 quence,

16                       “(ii) inhibit, eliminate, augment, or alter  
17 expression of an endogenous nucleotide se-  
18 quence, or

19                       “(iii) express a specific physiological char-  
20 acteristic not naturally associated with said or-  
21 ganism;

22               “(B) cell fusion procedures yielding a cell line  
23 that expresses a specific protein, such as a  
24 monoclonal antibody; and

1           “(C) a method of using a product produced by  
2           a process defined by (A) or (B), or a combination  
3           of (A) and (B).”.

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

5           Section 282 of title 35, United States Code, is  
6           amended by inserting after the second sentence of the first  
7           paragraph the following: “Notwithstanding the preceding  
8           sentence, if a claim to a composition of matter is held in-  
9           valid and that claim was the basis of a determination of  
10          nonobviousness under section 103(b)(1), the process shall  
11          no longer be considered nonobvious solely on the basis of  
12          section 103(b)(1).”.

13   **SEC. 3. EFFECTIVE DATE.**

14          The amendments made by section 1 shall apply to  
15          any application for patent filed on or after the date of  
16          enactment of this Act and to any application for patent  
17          pending on such date of enactment, including (in either  
18          case) an application for the reissuance of a patent.

          Passed the Senate September 28 (legislative day,  
September 25), 1995.

Attest:

*Secretary.*

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