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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.

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

A BILL

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

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. BIOTECHNOLOGICAL PROCESS PATENTS; CONDITIONS FOR PATENTABILITY; NONOBVIOUS SUBJECT MATTER.

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

HeinOnline -- 2 An Act to Amend Title 35, United States Code, with Respect to Patents on Biotechnological Processes, Pub. L. No.104-41, 109 Stat. 351 1 1995

(1) by designating the first paragraph as subsection (a);

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

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

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

"(A) claims to the process and the composition of matter are contained in either the same application for patent or in separate applications having the same effective filing date; and

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

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

"(A) shall also contain the claims to the composition of matter used in or made by that process, or

HeinOnline -- 2 An Act to Amend Title 35, United States Code, with Respect to Patents on Biotechnological Processes, Pub. L. No.104-41, 109 Stat. 351 2 1995

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

"(3) For purposes of paragraph (1), the term 'biotechnological process' means—

"(A) a process of genetically altering or otherwise inducing a single- or multi-celled organism to—

"(i) express an exogenous nucleotide sequence,

"(ii) inhibit, eliminate, augment, or alter expression of an endogenous nucleotide sequence, or

"(iii) express a specific physiological characteristic not naturally associated with said organism;

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

"(C) a method of using a product produced by a process defined by (A) or (B), or a combination of (A) and (B).".

SEC. 2. PRESUMPTION OF VALIDITY; DEFENSES.

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

HeinOnline -- 2 An Act to Amend Title 35, United States Code, with Respect to Patents on Biotechnological Processes, Pub. L. No.104-41, 109 Stat. 351 3 1995

paragraph the following: "Notwithstanding the preceding sentence, if a claim to a composition of matter is held invalid and that claim was the basis of a determination of nonobviousness under section 103(b)(1), the process shall no longer be considered nonobvious solely on the basis of section 103(b)(1).".

SEC. 3. EFFECTIVE DATE.

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

HeinOnline -- 2 An Act to Amend Title 35, United States Code, with Respect to Patents on Biotechnological Processes, Pub. L. No.104-41, 109 Stat. 351 4 1995

HeinOnline -- 2 An Act to Amend Title 35, United States Code, with Respect to Patents on Biotechnological Processes, Pub. L. No.104-41, 109 Stat. 351 [xiii] 1995

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SEPTEMBER 18 (legislative day, SEPTEMBER 5), 1995

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HeinOnline -- 2 An Act to Amend Title 35, United States Code, with Respect to Patents on Biotechnological Processes, Pub. L. No.104-41, 109 Stat. 351 [xiv] 1995

16)

HeinOnline -- 2 An Act to Amend Title 35, United States Code, with Respect to Patents on Biotechnological Processes, Pub. L. No.104-41, 109 Stat. 351 [xv] 1995

HeinOnline -- 2 An Act to Amend Title 35, United States Code, with Respect to Patents on Biotechnological Processes, Pub. L. No.104-41, 109 Stat. 351 [xvi] 1995