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Citation: 2 An Act to Amend Title 35 United States Code with
to Patents on Biotechnological Processes Pub. L.
109 Stat. 351 1 1995

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103D CONGRESS
1ST SESSION

S. 298

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

IN THE SENATE OF THE UNITED STATES

FEBRUARY 3 (legislative day, JANUARY 5), 1993

Mr. DECONCINI (for himself, Mr. HATCH, Mr. HEFLIN, Mr. KENNEDY, Mr. KOHL, Mr. LAUTENBERG, Mr. SPECTER, Mr. GRASSLEY, Mr. BROWN, and Mr. DOMENICI) introduced the following bill; which was read twice and 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.

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

TITLE I—BIOTECHNOLOGICAL PROCESS PATENTS

SEC. 101. CONDITIONS FOR PATENTABILITY; NONOBVIOUS SUBJECT MATTER.

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

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(1) in the first unnumbered paragraph by inserting "(a)" before "A patent";

(2) in the second unnumbered paragraph by inserting "(b)" before "Subject matter"; and

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

"(c) Notwithstanding any other provision of this section, a claimed process of making or using a machine, manufacture, or composition of matter is not obvious under this section if—

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

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

"(3)(A) the machine, manufacture, or composition of matter, and the claimed process invention at the time it was made, were owned by the same person or subject to an obligation of assignment to the same person; and

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

"(i) are entitled to the same effective filing date; and

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"(ii) appear in the same patent application, different patent applications, or patent which is owned by the same person and which expires or is set to expire on the same date.

"(d) For purposes of this section, the term 'biotechnological process' means any method of making or using living organisms, or parts thereof, for the purpose of making or modifying products. Such term includes recombinant DNA, recombinant RNA, cell fusion including hybridoma techniques, and other processes involving site specific manipulation of genetic material.".

SEC. 102. NO PRESUMPTION OF INVALIDITY.

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

SEC. 103. EFFECTIVE DATE.

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

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

TITLE II—BIOTECHNOLOGICAL MATERIAL PATENTS

SEC. 201. INFRINGEMENT BY IMPORTATION, SALE OR USE.

(a) INFRINGEMENT.—Section 271 of title 35, United States Code, is amended by adding at the end the following new subsection:

"(h) Whoever without authority imports into the United States or sells or uses within the United States a product which is made by using a biotechnological material (as defined under section 154(b)) which is patented in the United States shall be liable as an infringer if the importation, sale, or use of the product occurs during the term of such patent.".

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

(1) by inserting "(a)" before "Every";

(2) by striking out "in this title," and inserting in lieu thereof "in this title (1)";

(3) by striking out "and, if the invention" and inserting "(2) if the invention";

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(4) by inserting after "products made by that process," the following: "and (3) if the invention is a biotechnological material used in making a product, of the right to exclude others from using or selling throughout the United States, or importing into the United States the product made or using such biotechnological material,"; and

(5) by adding at the end thereof the following: "(b) For purposes of this section, the term 'biotechnological material' is defined as any material (including a host cell, DNA sequence, or vector) that is used in a biotechnological process as defined under section 103(d).".

(c) EFFECTIVE DATE.—

(1) IN GENERAL.—The amendment made by this section shall take effect six months after the date of enactment of this Act and, subject to paragraph (2), shall apply only with respect to products made or imported after the effective date of the amendments made by this section.

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

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

(B) to continue to use, sell, or import products for which substantial preparation by such person for such sale or use was made before such date, to the extent equitable for the protection of commercial investment made or business commenced in the United States before such date.

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