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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

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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