

103^D CONGRESS
1ST SESSION

S. 387

To amend title 35, United States Code, to impose a 2-year moratorium on the patenting of certain human tissues and organs, on human gene cells and on animal organisms, in order to provide time for Congress to fully assess, consider and respond to the economic, environmental and ethical issues raised by the patenting of such entities, and for other purposes.

IN THE SENATE OF THE UNITED STATES

FEBRUARY 18 (legislative day, JANUARY 5), 1993

Mr. HATFIELD 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, to impose a 2-year moratorium on the patenting of certain human tissues and organs, on human gene cells and on animal organisms, in order to provide time for Congress to fully assess, consider and respond to the economic, environmental and ethical issues raised by the patenting of such entities, and for other purposes.

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. SHORT TITLE.**

4 This Act may be cited as the “Life Patenting Morato-
5 rium Act of 1993”.

1 **SEC. 2. FINDINGS.**

2 The Congress finds the following:

3 (1) The rapid advances in biotechnology and
4 biomedical research capabilities are creating a wide
5 range of ethical, legal, economic, environmental,
6 international and social issues, including concerns
7 about the patenting of life forms, eugenics, genetic
8 discrimination, conflicts of interest for biomedical re-
9 searchers, and genetic privacy considerations in in-
10 surance and employment.

11 (2) Prominent members of the scientific com-
12 munity are discussing the possibility of the perma-
13 nent alteration of the genetic code of human beings
14 (referred to as “germ-line research”), yet Congress
15 has not yet addressed the ethical, legal, economic,
16 environmental, evolutionary, international and social
17 implications of such experimentation.

18 (3) The National Institutes of Health has al-
19 ready proposed patenting over 2,000 human gene se-
20 quences, an issue which raises unique and unprece-
21 dented ethical, legal, economic and social questions.

22 (4) Prior to the Patent and Trademark Office
23 policy of patenting animals, established on April 7,
24 1987, no animal had ever been patented under the
25 patent laws of the United States.

1 (5) Over 150 animal patents are presently
2 pending and three more were granted by the Patent
3 and Trademark Office of the Department of Com-
4 merce in December of 1992, in spite of the undeter-
5 mined ethical implications of such patents.

6 (6) Congress may act to significantly restrict or
7 alter the Patent and Trademark Office policy of pat-
8 enting animals and human genes.

9 (7) The Office of Technology Assessment will
10 complete a comprehensive review of these issues, and
11 the Congress is prepared to schedule hearings and
12 debate on this issue in the spring of 1993.

13 **SEC. 3. RESTRICTION ON THE ISSUANCE OF PATENTS.**

14 (a) IN GENERAL.—Chapter 10 of part II of title 35,
15 United States Code, is amended by adding at the end
16 thereof the following new section:

17 **“§ 106. Prohibition on Patentability of Certain Bio-**
18 **medical Inventions or Processes**

19 “(a) IN GENERAL.—No human being, human organ,
20 organ subpart (genetically engineered or otherwise) or ge-
21 netically engineered animal shall be considered patentable
22 subject matter under this title.

23 “(b) SUSPENSION.—Except as otherwise provided in
24 section, during the 2-year period beginning on the date
25 of enactment of this section, no—

1 “(1) human tissue, fluid, cell, gene or gene se-
2 quence (genetically engineered or otherwise); or

3 “(2) animal or animal organism (genetically en-
4 gineered or otherwise);

5 shall be considered patentable subject matter under this
6 title. The prohibition under this section may continue after
7 such 2-year period pursuant to section 381(f) of the Public
8 Health Service Act.

9 “(c) EXCEPTION.—Subsection (b) shall not apply to
10 patents issued prior to the date of enactment of this sec-
11 tion.

12 “(d) PATENT STATUS OF OTHERS.—Notwithstand-
13 ing any other provision of law, with respect to those indi-
14 viduals who have applied or will apply for a patent to
15 which this section applies, this section shall not be con-
16 strued to detrimentally affect the rights of such individ-
17 uals, but rather to maintain such rights until the expira-
18 tion of the 2-year period described in subsection (b).

19 “(e) DEFINITIONS.—As used in this section, the term
20 ‘genetically engineered’ means the formation of new com-
21 binations of genetic material by the insertion of nucleic
22 acid molecules into the host organism’s somatic or germ-
23 line cells so as to allow the incorporation of the new ge-
24 netic material into the genetic material of the host orga-
25 nism.”.

1 (b) CONFORMING AMENDMENT.—The table of sec-
2 tions for chapter 10 of part II of title 35, United States
3 Code, is amended by adding at the end thereof the follow-
4 ing:

“106. Prohibition on patentability of certain biomedical inventions or pro-
cesses.”.

5 **SEC. 4. SENSE OF THE CONGRESS.**

6 It is the sense of the Congress that—

7 (1) mindful of the dangers inherent in the un-
8 controlled patenting and proliferation of genetic ma-
9 terial, including problems in the areas of patenting
10 of life, eugenics, genetic discrimination, unexpected
11 and reproducible mutations, conflicts of interest for
12 biomedical researchers, and genetic privacy consider-
13 ations in insurance and employment, but aware of
14 the urgent need of humanity to reap the benefits of
15 responsibly-conducted research and innovation, legis-
16 lation addressing the implications of genetic research
17 should be thoroughly studied, considered, debated
18 and passed by the Congress as soon as reasonably
19 possible; and

20 (2) the Department of Commerce, the National
21 Institutes of Health and the Department of State
22 should work with the international community to de-
23 velop international standards relating to the patent-

- 1 ing of genetic information and access to such infor-
- 2 mation.

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