EXHIBIT 21

103D 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

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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.

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

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Life Patenting Moratorium Act of 1993''.

SEC. 2. FINDINGS.

The Congress finds the following:

(1) The rapid advances in biotechnology and biomedical research capabilities are creating a wide range of ethical, legal, economic, environmental, international and social issues, including concerns about the patenting of life forms, eugenics, genetic discrimination, conflicts of interest for biomedical researchers, and genetic privacy considerations in insurance and employment.

(2) Prominent members of the scientific community are discussing the possibility of the permanent alteration of the genetic code of human beings (referred to as ''germ-line research''), yet Congress has not yet addressed the ethical, legal, economic, environmental, evolutionary, international and social implications of such experimentation.

(3) The National Institutes of Health has already proposed patenting over 2,000 human gene sequences, an issue which raises unique and unprecedented ethical, legal, economic and social questions.

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

(5) Over 150 animal patents are presently pending and three more were granted by the Patent and Trademark Office of the Department of Commerce in December of 1992, in spite of the undetermined ethical implications of such patents.

(6) Congress may act to significantly restrict or alter the Patent and Trademark Office policy of patenting animals and human genes.

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

SEC. 3. RESTRICTION ON THE ISSUANCE OF PATENTS.

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

"§106. Prohibition on Patentability of Certain Biomedical Inventions or Processes

''(a) IN GENERAL.—No human being, human organ, organ subpart (genetically engineered or otherwise) or genetically engineered animal shall be considered patentable subject matter under this title.

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

''(1) human tissue, fluid, cell, gene or gene sequence (genetically engineered or otherwise); or

''(2) animal or animal organism (genetically engineered or otherwise);

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

''(c) EXCEPTION.—Subsection (b) shall not apply to patents issued prior to the date of enactment of this section.

''(d) PATENT STATUS OF OTHERS.—Notwithstanding any other provision of law, with respect to those individuals who have applied or will apply for a patent to which this section applies, this section shall not be construed to detrimentally affect the rights of such individuals, but rather to maintain such rights until the expiration of the 2-year period described in subsection (b).

''(e) DEFINITIONS.—As used in this section, the term 'genetically engineered' means the formation of new combinations of genetic material by the insertion of nucleic acid molecules into the host organism's somatic or germline cells so as to allow the incorporation of the new genetic material into the genetic material of the host organism.''.

(b) CONFORMING AMENDMENT.—The table of sections for chapter 10 of part II of title 35, United States Code, is amended by adding at the end thereof the following:

''106. Prohibition on patentability of certain biomedical inventions or processes.''.

SEC. 4. SENSE OF THE CONGRESS.

It is the sense of the Congress that—

(1) mindful of the dangers inherent in the uncontrolled patenting and proliferation of genetic material, including problems in the areas of patenting of life, eugenics, genetic discrimination, unexpected and reproducible mutations, conflicts of interest for biomedical researchers, and genetic privacy considerations in insurance and employment, but aware of the urgent need of humanity to reap the benefits of responsibly-conducted research and innovation, legislation addressing the implications of genetic research should be thoroughly studied, considered, debated and passed by the Congress as soon as reasonably possible; and

(2) the Department of Commerce, the National Institutes of Health and the Department of State should work with the international community to develop international standards relating to the patent-

ing of genetic information and access to such information.

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