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104TH CONGRESS
1ST SESSION

H. R. 587

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

IN THE HOUSE OF REPRESENTATIVES

JANUARY 19, 1995

Mr. MOORHEAD (for himself, Mr. BOUCHER, Mr. SENSENBRENNER, Mr. COBLE, Mr. FRANK of Massachusetts, Mr. GALLEGLY, Mr. GOODLATTE, Mr. GEKAS, Mr. BONO, Mr. CANADY of Florida, and Mr. HOKE) introduced the following bill; which was 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 biotechnological processes.

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

BIOTECHNOLOGICAL PROCESS PATENTS

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

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

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

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(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

"(B) shall, if such composition of matter is claimed in another patent, be set to expire on the

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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. 102. PRESUMPTION OF VALIDITY; DEFENSES.

Section 282 of title 35, United States Code, is amended by inserting after the second sentence of the first paragraph the following: "Notwithstanding the preceding sentence, if a claim to a composition of matter is held in-

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valid 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. 103. EFFECTIVE DATE.

The amendments made by section 101 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.

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