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107TH CONGRESS
2D SESSION

H. R. 3967

To amend title 35, United States Code, to provide for noninfringing uses of patents on genetic sequence information for purposes of research and genetic diagnostic testing, and to require public disclosure of such information in certain patent applications.

IN THE HOUSE OF REPRESENTATIVES

MARCH 14, 2002

Ms. RIVERS (for herself and Mr. WELDON of Florida) 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, to provide for noninfringing uses of patents on genetic sequence information for purposes of research and genetic diagnostic testing, and to require public disclosure of such information in certain patent applications.

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 ''Genomic Research and Diagnostic Accessibility Act of 2002''.

SEC. 2. EXEMPTION FROM INFRINGEMENT FOR RESEARCH ON GENETIC SEQUENCE INFORMATION.

Section 271 of title 35, United States Code, is amended by adding at the end thereof the following new subsection:

''(j) USE OF GENETIC SEQUENCE INFORMATION.—(1) It shall not be an act of infringement for any individual or entity to use any patent for or patented use of genetic sequence information for purposes of research. This paragraph shall not apply to any individual or entity that is directly engaged in the commercial manufacture, commercial sale, or commercial offer for sale of a drug, medical device, process, or other product using such patent for or patented use of genetic sequence information.

''(2) For purposes of this subsection—

''(A) the term 'device' has the same meaning as defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(h));

''(B) the term 'genetic sequence information' means any ordered listing of nucleotides comprising a portion of an organism's genetic code;

''(C) the term 'drug' has the same meaning as defined in section 201(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(g));

''(D) the term 'product' means a machine, manufacture, or composition of matter or improvement thereof; and

''(E) the term 'research' means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.''.

SEC. 3. EXEMPTION FROM INFRINGEMENT REMEDIES FOR GENETIC DIAGNOSTIC TESTING.

(a) EXEMPTION.—Section 287(c)(2) of title 35, United States Code, is amended—

(1) by amending subparagraph (A) to read as follows:

''(A) the term 'medical activity' means the performance of a genetic diagnostic, prognostic, or predictive test or a medical or surgical procedure.'';

(2) by redesignating subparagraphs (F) and (G) as subparagraphs (G) and (H), respectively; and

(3) by inserting after subparagraph (E) the following:

''(F) the term 'genetic diagnostic, prognostic, or predictive test' means any test, designed to detect disease, to predict the potential for a medical disorder, or to predict the effectiveness of therapeutics, which uses either an ordered listing of nucleotides

comprising a portion of a human or human pathogen genetic code or the proteins encoded by such nucleotides.''.

(b) REPEAL.—Section 287(c)(3) of title 35, United States Code, is repealed.

(c) APPLICABILITY.—Notwithstanding section 287(c)(4) of of title 35, United States Code, the amendments made by subsection (a) shall not apply to any patent issued based on an application the earliest effective filing date of which is before the date of the enactment of this Act.

SEC. 4. PUBLIC DISCLOSURE OF GENETIC SEQUENCE INFORMATION IN FEDERAL AND FEDERALLY ASSISTED PATENTS.

(a) STATEMENT OF POLICY AND OBJECTIVES.—Section 200 of title 35, United States Code, is amended by inserting ''to promote the informational value of patents;'' after ''United States industry and labor;''.

(b) DISPOSITION OF RIGHTS.—Section 202(c) of title 35, United States Code, is amended by adding at the end the following new paragraph:

''(9) That the contractor, not later than 30 days after the date on which the contractor files an application for a patent on a subject invention which involves a patent for, or a patent for use of, genetic

sequence information (as defined in section 271(j)(2)(B)), make that information public. This paragraph applies in lieu of any provision of section 122.''.

(c) CONFIDENTIALITY.—Section 205 of title 35, United States Code, is amended by adding at the end the following new sentence: ''In any case, any Federal agency filing an application for patent on genetic sequence information (as defined in section 271(j)(2)(B)) shall (subject to section 181) disclose that information to the public not later than 30 days after filing the application. This paragraph applies in lieu of any provision of section 122.''.

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