

EXHIBIT

19

107TH CONGRESS
2^D 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

A BILL

To amend title 35, United States Code, to provide for non-infringing 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.

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 “Genomic Research and
5 Diagnostic Accessibility Act of 2002”.

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

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

6 “(j) USE OF GENETIC SEQUENCE INFORMATION.—

7 (1) It shall not be an act of infringement for any indi-
8 vidual or entity to use any patent for or patented use of
9 genetic sequence information for purposes of research.
10 This paragraph shall not apply to any individual or entity
11 that is directly engaged in the commercial manufacture,
12 commercial sale, or commercial offer for sale of a drug,
13 medical device, process, or other product using such pat-
14 ent for or patented use of genetic sequence information.

15 “(2) For purposes of this subsection—

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

19 “(B) the term ‘genetic sequence information’
20 means any ordered listing of nucleotides comprising
21 a portion of an organism’s genetic code;

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

1 “(D) the term ‘product’ means a machine, man-
2 ufacture, or composition of matter or improvement
3 thereof; and

4 “(E) the term ‘research’ means a systematic in-
5 vestigation, including research development, testing,
6 and evaluation, designed to develop or contribute to
7 generalizable knowledge.”.

8 **SEC. 3. EXEMPTION FROM INFRINGEMENT REMEDIES FOR**
9 **GENETIC DIAGNOSTIC TESTING.**

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

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

14 “(A) the term ‘medical activity’ means the per-
15 formance of a genetic diagnostic, prognostic, or pre-
16 dictive test or a medical or surgical procedure.”;

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

19 (3) by inserting after subparagraph (E) the fol-
20 lowing:

21 “(F) the term ‘genetic diagnostic, prognostic, or
22 predictive test’ means any test, designed to detect
23 disease, to predict the potential for a medical dis-
24 order, or to predict the effectiveness of therapeutics,
25 which uses either an ordered listing of nucleotides

1 comprising a portion of a human or human pathogen
2 genetic code or the proteins encoded by such nucleo-
3 tides.”.

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

6 (c) APPLICABILITY.—Notwithstanding section
7 287(c)(4) of of title 35, United States Code, the amend-
8 ments made by subsection (a) shall not apply to any pat-
9 ent issued based on an application the earliest effective
10 filing date of which is before the date of the enactment
11 of this Act.

12 **SEC. 4. PUBLIC DISCLOSURE OF GENETIC SEQUENCE IN-**
13 **FORMATION IN FEDERAL AND FEDERALLY**
14 **ASSISTED PATENTS.**

15 (a) STATEMENT OF POLICY AND OBJECTIVES.—Sec-
16 tion 200 of title 35, United States Code, is amended by
17 inserting “to promote the informational value of patents;”
18 after “United States industry and labor;”.

19 (b) DISPOSITION OF RIGHTS.—Section 202(c) of title
20 35, United States Code, is amended by adding at the end
21 the following new paragraph:

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

1 sequence information (as defined in section
2 271(j)(2)(B)), make that information public. This
3 paragraph applies in lieu of any provision of section
4 122.”.

5 (c) CONFIDENTIALITY.—Section 205 of title 35,
6 United States Code, is amended by adding at the end the
7 following new sentence: “In any case, any Federal agency
8 filing an application for patent on genetic sequence infor-
9 mation (as defined in section 271(j)(2)(B)) shall (subject
10 to section 181) disclose that information to the public not
11 later than 30 days after filing the application. This para-
12 graph applies in lieu of any provision of section 122.”.

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