

104TH CONGRESS
2D SESSION

S. 2105

To amend chapter 29 of title 35, United States Code, to provide for a limitation on patent infringements relating to a medical practitioner's performance of a medical activity.

IN THE SENATE OF THE UNITED STATES

SEPTEMBER 24 (legislative day, SEPTEMBER 20), 1996

Mr. FRIST introduced the following bill; which was read twice and referred to the Committee on the Judiciary

A BILL

To amend chapter 29 of title 35, United States Code, to provide for a limitation on patent infringements relating to a medical practitioner's performance of a medical activity.

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. LIMITATION ON PATENT INFRINGEMENTS RE-**
4 **LATING TO A MEDICAL PRACTITIONER'S PER-**
5 **FORMANCE OF A MEDICAL ACTIVITY.**

6 Section 287 of title 35, United States Code, is
7 amended by adding at the end the following new sub-
8 section:

1 “(c)(1) With respect to a medical practitioner’s per-
2 formance of a medical activity that constitutes an infringe-
3 ment under section 271 (a) or (b) of this title, the provi-
4 sions of sections 281, 283, 284, and 285 of this title shall
5 not apply against the medical practitioner or against a re-
6 lated health care entity with respect to such medical activ-
7 ity.

8 “(2) This subsection does not apply to the activities
9 of any person, or employee or agent of such person (re-
10 gardless of whether such person is a tax exempt organiza-
11 tion under section 501(c) of the Internal Revenue Code
12 of 1986), who is engaged in the commercial development,
13 manufacture, sale, importation, or distribution of a ma-
14 chine, manufacture, or composition of matter or the provi-
15 sion of pharmacy or clinical laboratory services (other
16 than laboratory services provided in a physician’s office),
17 if such activities are—

18 “(A) directly related to the commercial develop-
19 ment, manufacture, sale, importation, or distribution
20 of a machine, manufacture, or composition of matter
21 or the provision of pharmacy or clinical laboratory
22 services (other than clinical laboratory services pro-
23 vided in a physician’s office); and

1 “(B) regulated under the Federal Food, Drug,
2 and Cosmetic Act, the Public Health Service Act, or
3 the Clinical Laboratories Improvement Act.

4 “(3) For purposes of this subsection:

5 “(A) The term ‘body’ means—

6 “(i) a human body, organ, or cadaver; or

7 “(ii) a nonhuman animal used in medical
8 research or instruction directly relating to the
9 treatment of humans.

10 “(B) The term ‘medical activity’ means the per-
11 formance of a medical or surgical procedure on a
12 body, but shall not include—

13 “(i) the use of a patented machine, manu-
14 facture, or composition of matter in violation of
15 such patent;

16 “(ii) the practice of a patented use of a
17 composition of matter in violation of such pat-
18 ent; or

19 “(iii) the practice of a process in violation
20 of a biotechnology patent.

21 “(C) The term ‘medical practitioner’ means any
22 natural person who is—

23 “(i) licensed by a State to provide the med-
24 ical activity described under paragraph (1); or

1 “(ii) acting under the direction of such
2 natural person in the performance of the medi-
3 cal activity.

4 “(D) The term ‘patented use of a composition
5 of matter’ does not include a claim for a method of
6 performing a medical or surgical procedure on a
7 body that recites the use of a composition of matter
8 if the use of that composition of matter does not di-
9 rectly contribute to achievement of the objective of
10 the claimed method.

11 “(E) The term ‘professional affiliation’ means
12 staff privileges, medical staff membership, employ-
13 ment or contractual relationship, partnership or
14 ownership interest, academic appointment, or other
15 affiliation under which a medical practitioner pro-
16 vides a medical activity on behalf of, or in associa-
17 tion with, a health care entity.

18 “(F) The term ‘related health care entity’—

19 “(i) means an entity with which a medical
20 practitioner has a professional affiliation under
21 which the medical practitioner performs a medi-
22 cal activity; and

23 “(ii) includes without limitation such an
24 affiliation with a nursing home, hospital, uni-
25 versity, medical school, health maintenance or-

1 ganization, group medical practice, or a medical
2 clinic.

3 “(G) The term ‘State’ means any State or terri-
4 tory of the United States, the District of Columbia,
5 and the Commonwealth of Puerto Rico.

6 “(4) This subsection shall not apply to any patent
7 issued before the date of enactment of this subsection.”.

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