OLL24005 W57 S.L.C.

| 118TH CONGRESS 2D SESSION | S. | |
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To address patent thickets.

IN THE SENATE OF THE UNITED STATES

Mr. Welch (for himself, Mr. Braun, and Ms. Klobuchar) introduced the following bill; which was read twice and referred to the Committee on

A BILL

To address patent thickets.

- 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. ADDRESSING PATENT THICKETS.
- 4 (a) Limit on Number of Patents Per Patent
- 5 Group That May Be Asserted in Action for In-
- 6 FRINGEMENT.—Section 271(e) of title 35, United States
- 7 Code, is amended by adding at the end the following:
- 8 "(7)(A) A person who brings an action for infringe-
- 9 ment of a patent under this section against a party de-
- 10 scribed in subparagraph (B) may assert in the action not
- 11 more than one patent per Patent Group.

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| 1 | "(B) A party described in this subparagraph is— |
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| 2 | "(i) a person who— |
| 3 | "(I) submits an application for approval of |
| 4 | a drug under subsection (b)(2) or (j) of section |
| 5 | 505 of the Federal Food, Drug, and Cosmetic |
| 6 | Act (21 U.S.C. 355), or is a holder of such an |
| 7 | approved application; or |
| 8 | "(II) submits an application for licensure |
| 9 | of a biological product under section 351(k) of |
| 10 | the Public Health Service Act (42 U.S.C. |
| 11 | 262(k)), or is a holder of such a licensure; or |
| 12 | "(ii) a person making, using, selling, offering |
| 13 | for sale, introducing or delivering into interstate |
| 14 | commerce, or importing— |
| 15 | "(I) a drug approved pursuant to an appli- |
| 16 | cation under subsection (b)(2) or (j) of section |
| 17 | 505 of the Federal Food, Drug, and Cosmetic |
| 18 | Act (21 U.S.C. 355); or |
| 19 | "(II) a biological product licensed under |
| 20 | section 351(k) of the Public Health Service Act |
| 21 | (42 U.S.C. 262(k)). |
| 22 | "(C) A person who brings an action described in sub- |
| 23 | paragraph (A) asserting a patent against a party may not |
| 24 | bring any additional actions described in that subpara- |

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graph asserting a patent in the same Patent Group 2 against that party. 3 "(D)(i) For purposes of this paragraph, the term 'Patent Group' means 2 or more commonly owned patents 4 5 or applications that— 6 "(I) are identified on 1 or more disclaimers 7 under section 253 to obviate obviousness-type double 8 patenting of another commonly owned patent; or 9 "(II) are subject to 1 or more disclaimers under 10 section 253 to obviate obviousness-type double pat-11 enting of another commonly owned patent. 12 "(ii) For purposes of clause (i)(I)— 13 "(I) each patent or application that identifies 14 the same patent or application on a disclaimer under 15 section 253 is part of the same Patent Group; and 16 "(II) each patent or application that is identi-17 fied on a disclaimer under section 253 is part of the 18 same Patent Group as the patent or application sub-19 ject to the disclaimer.". 20 (b) APPLICABILITY.—The amendment made by sub-21 section (a) shall apply with respect to an application sub-22 mitted under subsection (b)(2) or (j) of section 505 of the 23 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355)

or section 351(k) of the Public Health Service Act (42)

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1 U.S.C. 262(k)) on or after the date of enactment of this

2 Act.