119TH CONGRESS 1ST SESSION

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To address patent thickets.

## IN THE SENATE OF THE UNITED STATES

Mr. WELCH (for himself, Mr. HAWLEY, 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. SHORT TITLE.

4 This Act may be cited as the "Eliminating Thickets

5 to Increase Competition Act" or the "ETHIC Act".

## 6 SEC. 2. ADDRESSING PATENT THICKETS.

7 (a) LIMIT ON NUMBER OF PATENTS PER PATENT
8 GROUP THAT MAY BE ASSERTED IN ACTION FOR IN9 FRINGEMENT.—Section 271(e) of title 35, United States
10 Code, is amended by adding at the end the following:

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<ul> <li>4 more than one patent per Patent Group.</li> <li>5 "(B) A party described in this subparagraph is—</li> <li>6 "(i) a person who—</li> <li>7 "(I) submits an application for approval of</li> <li>8 a drug under subsection (b)(2) or (j) of section</li> <li>9 505 of the Federal Food, Drug, and Cosmetie</li> <li>10 Act (21 U.S.C. 355), or is a holder of such an</li> <li>11 approved application; or</li> <li>12 "(II) submits an application for licensure</li> <li>13 of a biological product under section 351(k) of</li> <li>14 the Public Health Service Act (42 U.S.C.</li> <li>15 262(k)), or is a holder of such a licensure; or</li> <li>16 "(ii) a person making, using, selling, offering</li> <li>17 for sale, introducing or delivering into interstate</li> <li>18 commerce, or importing—</li> <li>19 "(I) a drug approved pursuant to an appli-</li> <li>20 cation under subsection (b)(2) or (j) of section</li> <li>21 505 of the Federal Food, Drug, and Cosmetie</li> <li>22 Act (21 U.S.C. 355); or</li> <li>23 "(II) a biological product licensed under</li> <li>24 section 351(k) of the Public Health Service Act</li> </ul>	1	"(7)(A) A person who brings an action for infringe-
<ul> <li>4 more than one patent per Patent Group.</li> <li>5 "(B) A party described in this subparagraph is—</li> <li>6 "(i) a person who—</li> <li>7 "(I) submits an application for approval of</li> <li>8 a drug under subsection (b)(2) or (j) of section</li> <li>9 505 of the Federal Food, Drug, and Cosmetie</li> <li>10 Act (21 U.S.C. 355), or is a holder of such an</li> <li>11 approved application; or</li> <li>12 "(II) submits an application for licensure</li> <li>13 of a biological product under section 351(k) of</li> <li>14 the Public Health Service Act (42 U.S.C.</li> <li>15 262(k)), or is a holder of such a licensure; or</li> <li>16 "(ii) a person making, using, selling, offering</li> <li>17 for sale, introducing or delivering into interstate</li> <li>18 commerce, or importing—</li> <li>19 "(I) a drug approved pursuant to an appli-</li> <li>20 cation under subsection (b)(2) or (j) of section</li> <li>21 505 of the Federal Food, Drug, and Cosmetie</li> <li>22 Act (21 U.S.C. 355); or</li> <li>23 "(II) a biological product licensed under</li> <li>24 section 351(k) of the Public Health Service Act</li> </ul>	2	ment of a patent under this section against a party de-
<ul> <li>"(B) A party described in this subparagraph is—</li> <li>"(i) a person who—</li> <li>"(i) submits an application for approval of</li> <li>a drug under subsection (b)(2) or (j) of section</li> <li>505 of the Federal Food, Drug, and Cosmetic</li> <li>Act (21 U.S.C. 355), or is a holder of such an</li> <li>approved application; or</li> <li>"(II) submits an application for licensure</li> <li>of a biological product under section 351(k) of</li> <li>the Public Health Service Act (42 U.S.C.</li> <li>262(k)), or is a holder of such a licensure; or</li> <li>"(ii) a person making, using, selling, offering</li> <li>for sale, introducing or delivering into interstate</li> <li>commerce, or importing—</li> <li>"(I) a drug approved pursuant to an appli-</li> <li>cation under subsection (b)(2) or (j) of section</li> <li>505 of the Federal Food, Drug, and Cosmetic</li> <li>Act (21 U.S.C. 355); or</li> <li>"(II) a biological product licensed under</li> <li>section 351(k) of the Public Health Service Act</li> </ul>	3	scribed in subparagraph (B) may assert in the action not
<ul> <li>6 "(i) a person who—</li> <li>7 "(I) submits an application for approval of</li> <li>8 a drug under subsection (b)(2) or (j) of section</li> <li>9 505 of the Federal Food, Drug, and Cosmetic</li> <li>10 Act (21 U.S.C. 355), or is a holder of such an</li> <li>11 approved application; or</li> <li>12 "(II) submits an application for licensure</li> <li>13 of a biological product under section 351(k) of</li> <li>14 the Public Health Service Act (42 U.S.C.</li> <li>15 262(k)), or is a holder of such a licensure; or</li> <li>16 "(ii) a person making, using, selling, offering</li> <li>17 for sale, introducing or delivering into interstate</li> <li>18 commerce, or importing—</li> <li>19 "(I) a drug approved pursuant to an appli-</li> <li>20 eation under subsection (b)(2) or (j) of section</li> <li>21 505 of the Federal Food, Drug, and Cosmetic</li> <li>22 Act (21 U.S.C. 355); or</li> <li>23 "(II) a biological product licensed under</li> <li>24 section 351(k) of the Public Health Service Act</li> </ul>	4	more than one patent per Patent Group.
<ul> <li>"(I) submits an application for approval of a drug under subsection (b)(2) or (j) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), or is a holder of such an approved application; or</li> <li>"(II) submits an application for licensure of a biological product under section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)), or is a holder of such a licensure; or</li> <li>"(ii) a person making, using, selling, offering for sale, introducing or delivering into interstate commerce, or importing—</li> <li>"(I) a drug approved pursuant to an appli- eation under subsection (b)(2) or (j) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355); or</li> <li>"(II) a biological product licensed under section 351(k) of the Public Health Service Act</li> </ul>	5	"(B) A party described in this subparagraph is—
8a drug under subsection (b)(2) or (j) of section9505 of the Federal Food, Drug, and Cosmetic10Act (21 U.S.C. 355), or is a holder of such an11approved application; or12"(II) submits an application for licensure13of a biological product under section 351(k) of14the Public Health Service Act (42 U.S.C.15262(k)), or is a holder of such a licensure; or16"(ii) a person making, using, selling, offering17for sale, introducing or delivering into interstate18commerce, or importing—19"(I) a drug approved pursuant to an appli-20eation under subsection (b)(2) or (j) of section21505 of the Federal Food, Drug, and Cosmetic22Act (21 U.S.C. 355); or23"(II) a biological product licensed under24section 351(k) of the Public Health Service Act	6	"(i) a person who—
<ul> <li>9 505 of the Federal Food, Drug, and Cosmetic</li> <li>10 Act (21 U.S.C. 355), or is a holder of such an</li> <li>11 approved application; or</li> <li>12 "(II) submits an application for licensure</li> <li>13 of a biological product under section 351(k) of</li> <li>14 the Public Health Service Act (42 U.S.C.</li> <li>15 262(k)), or is a holder of such a licensure; or</li> <li>16 "(ii) a person making, using, selling, offering</li> <li>17 for sale, introducing or delivering into interstate</li> <li>18 commerce, or importing—</li> <li>19 "(I) a drug approved pursuant to an appli-</li> <li>20 cation under subsection (b)(2) or (j) of section</li> <li>21 505 of the Federal Food, Drug, and Cosmetie</li> <li>22 Act (21 U.S.C. 355); or</li> <li>23 "(II) a biological product licensed under</li> <li>24 section 351(k) of the Public Health Service Act</li> </ul>	7	"(I) submits an application for approval of
10Act (21 U.S.C. 355), or is a holder of such an approved application; or11approved application; or12"(II) submits an application for licensure of a biological product under section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)), or is a holder of such a licensure; or "(ii) a person making, using, selling, offering for sale, introducing or delivering into interstate commerce, or importing—19"(I) a drug approved pursuant to an appli- cation under subsection (b)(2) or (j) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355); or23"(II) a biological product licensed under section 351(k) of the Public Health Service Act	8	a drug under subsection $(b)(2)$ or $(j)$ of section
11approved application; or12"(II) submits an application for licensure13of a biological product under section 351(k) of14the Public Health Service Act (42 U.S.C.15262(k)), or is a holder of such a licensure; or16"(ii) a person making, using, selling, offering17for sale, introducing or delivering into interstate18commerce, or importing—19"(I) a drug approved pursuant to an appli-20cation under subsection (b)(2) or (j) of section21505 of the Federal Food, Drug, and Cosmetic22Act (21 U.S.C. 355); or23"(II) a biological product licensed under24section 351(k) of the Public Health Service Act	9	505 of the Federal Food, Drug, and Cosmetic
<ul> <li>"(II) submits an application for licensure</li> <li>of a biological product under section 351(k) of</li> <li>the Public Health Service Act (42 U.S.C.</li> <li>262(k)), or is a holder of such a licensure; or</li> <li>"(ii) a person making, using, selling, offering</li> <li>for sale, introducing or delivering into interstate</li> <li>commerce, or importing—</li> <li>"(I) a drug approved pursuant to an appli-</li> <li>cation under subsection (b)(2) or (j) of section</li> <li>505 of the Federal Food, Drug, and Cosmetic</li> <li>Act (21 U.S.C. 355); or</li> <li>"(II) a biological product licensed under</li> <li>section 351(k) of the Public Health Service Act</li> </ul>	10	Act (21 U.S.C. 355), or is a holder of such an
<ul> <li>of a biological product under section 351(k) of</li> <li>the Public Health Service Act (42 U.S.C.</li> <li>262(k)), or is a holder of such a licensure; or</li> <li>"(ii) a person making, using, selling, offering</li> <li>for sale, introducing or delivering into interstate</li> <li>commerce, or importing—</li> <li>"(I) a drug approved pursuant to an appli-</li> <li>cation under subsection (b)(2) or (j) of section</li> <li>505 of the Federal Food, Drug, and Cosmetic</li> <li>Act (21 U.S.C. 355); or</li> <li>"(II) a biological product licensed under</li> <li>section 351(k) of the Public Health Service Act</li> </ul>	11	approved application; or
14the Public Health Service Act (42 U.S.C.15262(k)), or is a holder of such a licensure; or16"(ii) a person making, using, selling, offering17for sale, introducing or delivering into interstate18commerce, or importing—19"(I) a drug approved pursuant to an appli-20cation under subsection (b)(2) or (j) of section21505 of the Federal Food, Drug, and Cosmetic22Act (21 U.S.C. 355); or23"(II) a biological product licensed under24section 351(k) of the Public Health Service Act	12	"(II) submits an application for licensure
<ul> <li>15 262(k)), or is a holder of such a licensure; or</li> <li>16 "(ii) a person making, using, selling, offering</li> <li>17 for sale, introducing or delivering into interstate</li> <li>18 commerce, or importing—</li> <li>19 "(I) a drug approved pursuant to an appli-</li> <li>20 eation under subsection (b)(2) or (j) of section</li> <li>21 505 of the Federal Food, Drug, and Cosmetic</li> <li>22 Act (21 U.S.C. 355); or</li> <li>23 "(II) a biological product licensed under</li> <li>24 section 351(k) of the Public Health Service Act</li> </ul>	13	of a biological product under section 351(k) of
<ul> <li>"(ii) a person making, using, selling, offering</li> <li>for sale, introducing or delivering into interstate</li> <li>commerce, or importing—</li> <li>"(I) a drug approved pursuant to an appli-</li> <li>cation under subsection (b)(2) or (j) of section</li> <li>505 of the Federal Food, Drug, and Cosmetic</li> <li>Act (21 U.S.C. 355); or</li> <li>"(II) a biological product licensed under</li> <li>section 351(k) of the Public Health Service Act</li> </ul>	14	the Public Health Service Act (42 U.S.C.
<ul> <li>for sale, introducing or delivering into interstate</li> <li>commerce, or importing—</li> <li>"(I) a drug approved pursuant to an appli-</li> <li>cation under subsection (b)(2) or (j) of section</li> <li>505 of the Federal Food, Drug, and Cosmetic</li> <li>Act (21 U.S.C. 355); or</li> <li>"(II) a biological product licensed under</li> <li>section 351(k) of the Public Health Service Act</li> </ul>	15	262(k)), or is a holder of such a licensure; or
<ul> <li>commerce, or importing—</li> <li>"(I) a drug approved pursuant to an application under subsection (b)(2) or (j) of section</li> <li>505 of the Federal Food, Drug, and Cosmetic</li> <li>Act (21 U.S.C. 355); or</li> <li>"(II) a biological product licensed under</li> <li>section 351(k) of the Public Health Service Act</li> </ul>	16	"(ii) a person making, using, selling, offering
<ul> <li>19 "(I) a drug approved pursuant to an appli-</li> <li>20 cation under subsection (b)(2) or (j) of section</li> <li>21 505 of the Federal Food, Drug, and Cosmetic</li> <li>22 Act (21 U.S.C. 355); or</li> <li>23 "(II) a biological product licensed under</li> <li>24 section 351(k) of the Public Health Service Act</li> </ul>	17	for sale, introducing or delivering into interstate
<ul> <li>cation under subsection (b)(2) or (j) of section</li> <li>505 of the Federal Food, Drug, and Cosmetic</li> <li>Act (21 U.S.C. 355); or</li> <li>"(II) a biological product licensed under</li> <li>section 351(k) of the Public Health Service Act</li> </ul>	18	commerce, or importing—
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<ul> <li>Act (21 U.S.C. 355); or</li> <li>"(II) a biological product licensed under</li> <li>section 351(k) of the Public Health Service Act</li> </ul>	20	cation under subsection $(b)(2)$ or $(j)$ of section
<ul> <li>23 "(II) a biological product licensed under</li> <li>24 section 351(k) of the Public Health Service Act</li> </ul>	21	505 of the Federal Food, Drug, and Cosmetic
24 section 351(k) of the Public Health Service Act	22	Act (21 U.S.C. 355); or
	23	"(II) a biological product licensed under
25 $(42 \text{ US} \mathbb{C} \ 262(\mathbf{k}))$	24	section 351(k) of the Public Health Service Act
(12 0.0.0.202(R))	25	(42 U.S.C. 262(k)).

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"(C) A person who brings an action described in sub paragraph (A) asserting a patent against a party may not
 bring any additional actions described in that subpara graph asserting a patent in the same Patent Group
 against that party.

6 "(D)(i) For purposes of this paragraph, the term
7 'Patent Group' means 2 or more commonly owned patents
8 or applications that—

9 "(I) are identified on 1 or more disclaimers
10 under section 253 to obviate obviousness-type double
11 patenting of another commonly owned patent; or

"(II) are subject to 1 or more disclaimers under
section 253 to obviate obviousness-type double patenting of another commonly owned patent.

15 "(ii) For purposes of clause (i)(I)—

"(I) each patent or application that identifies
the same patent or application on a disclaimer under
section 253 is part of the same Patent Group; and
"(II) each patent or application that is identified on a disclaimer under section 253 is part of the
same Patent Group as the patent or application subject to the disclaimer.".

(b) APPLICABILITY.—The amendment made by subsection (a) shall apply with respect to an application submitted under subsection (b)(2) or (j) of section 505 of the

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1 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355)

 $2~{\rm or~section}~351(k)$  of the Public Health Service Act (42

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

4 Act.