

AMENDMENT NO. \_\_\_\_\_

Calendar No. \_\_\_\_\_

Purpose: To improve the bill with respect to the protection of trade secret and confidential or financial information.

**IN THE SENATE OF THE UNITED STATES—119th Cong., 2d Sess.**

**S. 2658**

To require sponsors of drug applications and holders of approved applications to provide certain submissions and communications to the Food and Drug Administration and the United States Patent and Trademark Office.

Referred to the Committee on \_\_\_\_\_ and ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENTS intended to be proposed by Mr. BANKS

Viz:

1 On page 5, strike line 14 and all that follows through  
2 line 2 on page 6 and insert the following:

3 “(E)(i) Any information that the sponsor of the ap-  
4 plication or holder of the application has submitted to or  
5 received from the Food and Drug Administration that is  
6 submitted to the United States Patent and Trademark Of-  
7 fice to fulfill the requirements of subparagraph (A) shall  
8 remain subject to applicable protections for trade secret  
9 or confidential information or financial information (in-  
10 cluding section 1905 of title 18, United States Code, sec-  
11 tion 552 of title 5, United States Code, section 301(j) of

1 this Act, and part 20 of title 21, Code of Federal Regula-  
2 tions as in effect on the date of enactment of the Medica-  
3 tion Affordability and Patent Integrity Act), notwith-  
4 standing any contrary rules or practices, including those  
5 of the United States Patent and Trademark Office.”.

6 On page 6, strike lines 3 through 6 and insert the  
7 following:

8 “(ii) Before the United States Patent and  
9 Trademark Office publicly discloses any information  
10 that may constitute trade secret or confidential com-  
11 mercial or financial information and that is sub-  
12 mitted to such Office as described in subparagraph  
13 (A)(ii), such Office shall—

14 “(I) provide notice of such proposed disclo-  
15 sure to the sponsor of the application or holder  
16 of the approved application, as applicable, that  
17 submitted such information;

18 “(II) provide such sponsor or holder a pe-  
19 riod of 30 days to object to such proposed dis-  
20 closure, during which period the Office shall  
21 also redact trade secret or confidential commer-  
22 cial or financial information in each document;  
23 and

1           “(III) notwithstanding any other provision  
2 of law, provide a patent applicant the oppor-  
3 tunity to withdraw any relevant pending patent  
4 application in lieu of disclosure by the United  
5 States Patent and Trademark Office.

6           “(iii) The United States Patent and Trademark  
7 Office shall—

8           “(I) maintain any documents submitted to  
9 such Office to fulfill the requirements of sub-  
10 paragraph (A)(ii) separate from publicly avail-  
11 able records pertaining to pending patent appli-  
12 cations and issued patents;

13           “(II) establish procedures for the identi-  
14 fication of trade secret or confidential commer-  
15 cial or financial information in such documents  
16 and redaction of such information; and

17           “(III) not cite any trade secret or con-  
18 fidential commercial or financial information in  
19 any document that is released to the public.”.

20           On page 10, strike lines 10 through 23 and insert  
21 the following:

22           “(v)(I) Any information that the sponsor of the  
23 application or holder of the license has submitted to  
24 or received from the Food and Drug Administration

1 that is submitted to the United States Patent and  
2 Trademark office to fulfill the requirements of  
3 clause (i) shall remain subject to applicable protec-  
4 tions for trade secret or confidential information or  
5 financial information (including section 1905 of title  
6 18, United States Code, section 552 of title 5,  
7 United States Code, section 301(j) of the Federal  
8 Food, Drug, and Cosmetic Act, and part 20 of title  
9 21, Code of Federal Regulations as in effect on the  
10 date of enactment of the Medication Affordability  
11 and Patent Integrity Act), notwithstanding any con-  
12 trary rules or practices, including those of the  
13 United States Patent and Trademark Office.”.

14 On page 10, strike line 24 and all that follows  
15 through line 3 on page 11 and insert the following:

16 “(II) Before the United States Patent and  
17 Trademark Office publicly discloses any infor-  
18 mation that may constitute trade secret or con-  
19 fidential commercial or financial information  
20 and that is submitted to such Office as de-  
21 scribed in subparagraph (A)(ii), such Office  
22 shall—

23 “(aa) provide notice of such proposed  
24 disclosure to the sponsor of the application

1 or holder of the approved application, as  
2 applicable, that submitted such informa-  
3 tion;

4 “(bb) provide such sponsor or holder  
5 a period of 30 days to object to such pro-  
6 posed disclosure, during which period the  
7 Office shall also redact trade secret or con-  
8 fidential commercial or financial informa-  
9 tion in each document; and

10 “(cc) notwithstanding any other provi-  
11 sion of law, provide a patent applicant the  
12 opportunity to withdraw any relevant pend-  
13 ing patent application in lieu of disclosure  
14 by the United States Patent and Trade-  
15 mark Office.

16 “(III) The United States Patent and  
17 Trademark Office shall—

18 “(aa) maintain any documents sub-  
19 mitted to such Office to fulfill the require-  
20 ments of subparagraph (A)(ii) separate  
21 from publicly available records pertaining  
22 to pending patent applications and issued  
23 patents;

24 “(bb) establish procedures for the  
25 identification of trade secret or confidential

1 commercial or financial information in  
2 such documents and redaction of such in-  
3 formation; and  
4 “(cc) not cite any trade secret or con-  
5 fidential commercial or financial informa-  
6 tion in any document that is released to  
7 the public.”.