

117TH CONGRESS
2D SESSION

S. 4430

To amend title 35, United States Code, to establish an interagency task force between the United States Patent and Trademark Office and the Food and Drug Administration for purposes of sharing information and providing technical assistance with respect to patents, and for other purposes.

IN THE SENATE OF THE UNITED STATES

JUNE 16, 2022

Mr. DURBIN (for himself, Mr. TILLIS, and Mr. GRASSLEY) introduced the following bill; which was read twice and referred to the Committee on the Judiciary

A BILL

To amend title 35, United States Code, to establish an interagency task force between the United States Patent and Trademark Office and the Food and Drug Administration for purposes of sharing information and providing technical assistance with respect to patents, and for other purposes.

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 “Interagency Patent
5 Coordination and Improvement Act of 2022”.

1 **SEC. 2. FINDINGS.**

2 Congress finds the following:

3 (1) Decisions by the United States Patent and
4 Trademark Office relating to patents may implicate,
5 or have relevance to, information housed at or in-
6 volving other Federal agencies.

7 (2) Entities submitting patent applications to
8 the United States Patent and Trademark Office may
9 also submit information to, or share information
10 with, other Federal agencies, necessitating accuracy
11 and consistency in those representations.

12 (3) Research has shown that patent examiners
13 may benefit from additional information that is
14 housed at, or is available to, Federal agencies other
15 than the United States Patent and Trademark Of-
16 fice in order to assess prior art and the state of
17 science and technology.

18 (4) The Under Secretary of Commerce for In-
19 tellectual Property and Director of the United States
20 Patent and Trademark Office is encouraged to work
21 with other Federal agencies.

22 **SEC. 3. REPORT BY UNITED STATES PATENT AND TRADE-**
23 **MARK OFFICE.**

24 Not later than 4 years after the date of enactment
25 of this Act, the Under Secretary of Commerce for Intellec-
26 tual Property and Director of the United States Patent

1 and Trademark Office shall submit to the Committee on
2 the Judiciary of the Senate and the Committee on the Ju-
3 diciary of the House of Representatives a report that con-
4 tains—

5 (1) a description of the frequency with which—

6 (A) information is provided by the Food
7 and Drug Administration to the United States
8 Patent and Trademark Office through the
9 Interagency Task Force on Patents established
10 under section 15 of title 35, United States
11 Code, as added by section 4(a) of this Act, or
12 under processes established by that Task Force;
13 and

14 (B) the information described in subpara-
15 graph (A) is used in patent examinations;

16 (2) an identification of which methods of pro-
17 viding information, as described in paragraph
18 (1)(A), and types of information so shared, are most
19 useful to patent examiners;

20 (3) any recommendations for changes to be
21 made by Congress to the mandate, funding, or oper-
22 ations of the Task Force described in paragraph
23 (1)(A); and

24 (4) an identification of other Federal agencies
25 with which the Under Secretary of Commerce for In-

1 tellectual Property and Director of the United States
 2 Patent and Trademark Office should explore oppor-
 3 tunities for coordination that are similar to those
 4 undertaken with the Food and Drug Administration
 5 through the activities of the Task Force described in
 6 paragraph (1)(A).

7 **SEC. 4. INTERAGENCY TASK FORCE ON PATENTS.**

8 (a) IN GENERAL.—Chapter 1 of title 35, United
 9 States Code, is amended—

10 (1) in section 2(c), by adding at the end the fol-
 11 lowing:

12 “(6)(A) In exercising the Director’s powers and du-
 13 ties under this section relating to patents, and decisions
 14 or actions involving patents, for human drugs and biologi-
 15 cal products, the Director shall, through the Interagency
 16 Task Force on Patents established under section 15, con-
 17 sult with the Commissioner of Food and Drugs in the
 18 manner described in that section.

19 “(B) For purposes of subparagraph (A), the term
 20 ‘decisions or actions involving patents’ means decisions or
 21 actions taken with respect to patents under this title.”;
 22 and

23 (2) by adding at the end the following:

1 **“§ 15. Interagency Task Force on Patents**

2 “(a) ESTABLISHMENT.—There is established an
3 interagency task force, to be known as the Interagency
4 Task Force on Patents (referred to in this section as the
5 ‘task force’), to coordinate efforts between the Director
6 and the Commissioner of Food and Drugs (referred to in
7 this section as the ‘Commissioner’) regarding communica-
8 tion about, evaluation of, and effective implementation of
9 the activities of the Office and the Food and Drug Admin-
10 istration with respect to patents, and decisions or actions
11 involving patents (as defined in section 2(c)(6)(B)), for
12 human drugs and biological products.

13 “(b) MEMORANDUM OF UNDERSTANDING.—The Di-
14 rector and the Commissioner shall enter into a memo-
15 randum of understanding, or update an existing memo-
16 randum of understanding, for the purposes of imple-
17 menting and carrying out the duties of the task force.

18 “(c) MEMBERSHIP.—The task force shall be com-
19 prised of employees of the Office, who shall be appointed
20 by the Director, and employees of the Food and Drug Ad-
21 ministration, who shall be appointed by the Commissioner,
22 who have appropriate expertise and decision-making au-
23 thority regarding operational, administrative, technical,
24 medical, pharmacological, clinical, and scientific matters
25 to carry out the functions of the task force.

1 “(d) ACTIVITIES.—The task force shall carry out the
 2 following functions regarding interagency coordination to
 3 promote reciprocal access of information:

4 “(1) Sharing information on the general proc-
 5 esses of the Office and the Food and Drug Adminis-
 6 tration, what each such agency considers in its re-
 7 spective review of applications, and how each such
 8 agency evaluates those applications, which may be
 9 undertaken through routine and ongoing meetings,
 10 workshops, and training sessions.

11 “(2) Sharing information on new approvals of
 12 patents, human drugs and biological products, new
 13 technologies and prior art (as appropriate on a case-
 14 by-case basis), and scientific trends and develop-
 15 ments.

16 “(3) Establishing a process that requires—

17 “(A) the Director to request from the
 18 Commissioner (and the Commissioner to pro-
 19 vide to the Director, upon receiving such a re-
 20 quest)—

21 “(i) appropriate information for use
 22 by employees of the Office with responsi-
 23 bility to examine patent applications under
 24 section 131 (referred to in this section as
 25 ‘patent examiners’) regarding when certain

1 information relating to a human drug or
2 biological product approval, which may in-
3 clude updates to a label or newly approved
4 indications, is made publicly available, in-
5 cluding when such information is posted
6 online; and

7 “(ii) appropriate access for patent ex-
8 aminers to relevant sources of product ap-
9 plication, approval, patent, and labeling in-
10 formation or communications between the
11 Food and Drug Administration and the
12 prescription drug or biological product
13 sponsors that may not currently be subject
14 to public disclosure, as appropriate and
15 only to the extent necessary for the Office
16 to carry out the responsibilities of the Of-
17 fice, including ensuring accurate represen-
18 tations and the enforcement of the limita-
19 tion on granting a patent because the
20 claimed invention that would be the subject
21 of the patent was on sale before the effec-
22 tive filing date of the claimed invention, as
23 described in section 102(a)(1); and

24 “(B) the Office to assist the Food and
25 Drug Administration in its ministerial role of

1 listing appropriate and accurate descriptions of
2 patents.

3 “(4) Establishing a process to ensure that, in
4 appropriate circumstances, at the request of the Di-
5 rector, the Commissioner shall consult with or other-
6 wise furnish specific, available information to the Of-
7 fice with respect to certain applications, responses,
8 or affidavits after rejections in order to assist patent
9 examiners in carrying out the duties of those patent
10 examiners.

11 “(e) RULE OF CONSTRUCTION.—Nothing in sub-
12 section (d)(3)(B) shall be construed as—

13 “(1) directing the Office to interfere with or
14 delay the ministerial function of the Food and Drug
15 Administration of listing patents; or

16 “(2) indicating the position of the Office re-
17 garding the ability to assert a patent in infringement
18 litigation.

19 “(f) CONFIDENTIALITY.—

20 “(1) IN GENERAL.—The task force shall estab-
21 lish appropriate protocols to safeguard confiden-
22 tiality and prevent the inappropriate disclosure of in-
23 formation when sharing information between the Of-
24 fice and the Food and Drug Administration.

1 “(2) POTENTIAL REMEDIES.—In establishing
 2 protocols under paragraph (1), the task force shall
 3 identify appropriate remedies for any potential in-
 4 jury suffered when confidential information is made
 5 available, including inadvertently, through the shar-
 6 ing of information described in that paragraph.”.

7 (b) TECHNICAL AND CONFORMING AMENDMENT.—
 8 The table of sections for chapter 1 of title 35, United
 9 States Code, is amended by adding at the end the fol-
 10 lowing:

 “15. Interagency Task Force on Patents.”.

11 (c) AUTHORIZATION OF APPROPRIATIONS.—There
 12 are authorized to be appropriated to the Under Secretary
 13 of Commerce for Intellectual Property and Director of the
 14 United States Patent and Trademark Office and the Com-
 15 missioner of Food and Drugs such sums as may be nec-
 16 essary for the purposes of carrying out the functions of
 17 the Interagency Task Force on Patents established under
 18 section 15 of title 35, United States Code, as added by
 19 subsection (a).

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