

Calendar No. 463

117TH CONGRESS
2^D 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, Mr. GRASSLEY, Mr. LEAHY, Mr. COONS, and Mr. CORNYN) introduced the following bill; which was read twice and referred to the Committee on the Judiciary

AUGUST 2, 2022

Reported by Mr. DURBIN, with an amendment

[Strike out all after the enacting clause and insert the part printed in *italic*]

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,*

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Interagency Patent
3 Coordination and Improvement Act of 2022”.

4 **SEC. 2. FINDINGS.**

5 Congress finds the following:

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

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

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

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

1 **SEC. 3. REPORT BY UNITED STATES PATENT AND TRADE-**
2 **MARK OFFICE.**

3 Not later than 4 years after the date of enactment
4 of this Act, the Under Secretary of Commerce for Intellee-
5 tual Property and Director of the United States Patent
6 and Trademark Office shall submit to the Committee on
7 the Judiciary of the Senate and the Committee on the Ju-
8 diciary of the House of Representatives a report that con-
9 tains—

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

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

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

21 (2) an identification of which methods of pro-
22 viding information, as described in paragraph
23 (1)(A), and types of information so shared, are most
24 useful to patent examiners;

25 (3) any recommendations for changes to be
26 made by Congress to the mandate, funding, or oper-

1 ations of the Task Force described in paragraph
2 (1)(A); and

3 (4) an identification of other Federal agencies
4 with which the Under Secretary of Commerce for In-
5 tellectual Property and Director of the United States
6 Patent and Trademark Office should explore oppor-
7 tunities for coordination that are similar to those
8 undertaken with the Food and Drug Administration
9 through the activities of the Task Force described in
10 paragraph (1)(A).

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

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

14 (1) in section 2(e), by adding at the end the fol-
15 lowing:

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

23 “(B) For purposes of subparagraph (A), the term
24 ‘decisions or actions involving patents’ means decisions or

1 actions taken with respect to patents under this title.”;

2 and

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

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

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

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

21 “(c) MEMBERSHIP.—The task force shall be com-
22 prised of employees of the Office, who shall be appointed
23 by the Director, and employees of the Food and Drug Ad-
24 ministration, who shall be appointed by the Commissioner,
25 who have appropriate expertise and decision-making au-

1 thority regarding operational, administrative, technical,
 2 medical, pharmacological, clinical, and scientific matters
 3 to carry out the functions of the task force.

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

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

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

19 “(3) Establishing a process that requires—

20 “(A) the Director to request from the
 21 Commissioner (and the Commissioner to pro-
 22 vide to the Director, upon receiving such a re-
 23 quest)—

24 “(i) appropriate information for use
 25 by employees of the Office with responsi-

bility to examine patent applications under section 131 (referred to in this section as ‘patent examiners’) regarding when certain information relating to a human drug or biological product approval, which may include updates to a label or newly approved indications, is made publicly available, including when such information is posted online; and

“(ii) appropriate access for patent examiners to relevant sources of product application, approval, patent, and labeling information or communications between the Food and Drug Administration and the prescription drug or biological product sponsors that may not currently be subject to public disclosure, as appropriate and only to the extent necessary for the Office to carry out the responsibilities of the Office, including ensuring accurate representations and the enforcement of the limitation on granting a patent because the claimed invention that would be the subject of the patent was on sale before the effec-

1 tive filing date of the claimed invention; as
2 described in section 102(a)(1); and

3 ~~“(B) the Office to assist the Food and~~
4 ~~Drug Administration in its ministerial role of~~
5 ~~listing appropriate and accurate descriptions of~~
6 ~~patents.~~

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

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

17 ~~“(1) directing the Office to interfere with or~~
18 ~~delay the ministerial function of the Food and Drug~~
19 ~~Administration of listing patents; or~~

20 ~~“(2) indicating the position of the Office re-~~
21 ~~garding the ability to assert a patent in infringement~~
22 ~~litigation.~~

23 ~~“(f) CONFIDENTIALITY.—~~

24 ~~“(1) IN GENERAL.—The task force shall estab-~~
25 ~~lish appropriate protocols to safeguard confiden-~~

1 tiality and prevent the inappropriate disclosure of in-
 2 formation when sharing information between the Of-
 3 fice and the Food and Drug Administration.

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

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

“15. Interagency Task Force on Patents.”.

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

23 **SECTION 1. SHORT TITLE.**

24 *This Act may be cited as the “Interagency Patent Co-*
 25 *ordination 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 involv-*
6 *ing 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 Office*
16 *in order to assess prior art and the state of science*
17 *and technology.*

18 *(4) The Under Secretary of Commerce for Intel-*
19 *lectual 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 of*
25 *this Act, the Under Secretary of Commerce for Intellectual*
26 *Property and Director of the United States Patent and*

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

4 *(1) a description of the frequency with which—*

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

12 *(B) the information described in subpara-*
13 *graph (A) is used in patent examinations;*

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

18 *(3) any recommendations for changes to be made*
19 *by Congress to the mandate, funding, or operations of*
20 *the Task Force described in paragraph (1)(A); and*

21 *(4) an identification of other Federal agencies*
22 *with which the Under Secretary of Commerce for In-*
23 *tellectual Property and Director of the United States*
24 *Patent and Trademark Office should explore opportu-*
25 *nities for coordination that are similar to those un-*

1 *dertaken with the Food and Drug Administration*
 2 *through the activities of the Task Force described in*
 3 *paragraph (1)(A).*

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

5 *(a) IN GENERAL.—Chapter 1 of title 35, United States*
 6 *Code, is amended—*

7 *(1) in section 2(c), by adding at the end the fol-*
 8 *lowing:*

9 *“(6)(A) In exercising the Director’s powers and duties*
 10 *under this section relating to patents, and decisions or ac-*
 11 *tions involving patents, for human drugs and biological*
 12 *products, the Director shall, through the Interagency Task*
 13 *Force on Patents established under section 15, consult with*
 14 *the Commissioner of Food and Drugs in the manner de-*
 15 *scribed in that section.*

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

17 *(2) by adding at the end the following:*

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

19 *“(a) ESTABLISHMENT.—There is established an inter-*
 20 *agency task force, to be known as the Interagency Task*
 21 *Force on Patents (referred to in this section as the ‘task*
 22 *force’), to coordinate efforts between the Director and the*
 23 *Commissioner of Food and Drugs (referred to in this section*
 24 *under this title as the ‘Commissioner’).*

1 as the ‘Commissioner’) regarding communication about,
 2 evaluation of, and effective implementation of the activities
 3 of the Office and the Food and Drug Administration with
 4 respect to patents, and decisions or actions involving pat-
 5 ents (as defined in section 2(c)(6)(B)), for human drugs and
 6 biological products.

7 “(b) *MEMORANDUM OF UNDERSTANDING.*—The Direc-
 8 tor and the Commissioner shall enter into a memorandum
 9 of understanding, or update an existing memorandum of
 10 understanding, for the purposes of implementing and car-
 11 rying out the duties of the task force.

12 “(c) *MEMBERSHIP.*—The task force shall be comprised
 13 of employees of the Office, who shall be appointed by the
 14 Director, and employees of the Food and Drug Administra-
 15 tion, who shall be appointed by the Commissioner, who have
 16 appropriate expertise and decision-making authority re-
 17 garding operational, administrative, technical, medical,
 18 pharmacological, clinical, and scientific matters to carry
 19 out the functions of the task force.

20 “(d) *ACTIVITIES.*—The task force shall carry out the
 21 following functions regarding interagency coordination to
 22 promote reciprocal access of information:

23 “(1) *Sharing information on the general proc-*
 24 *esses of the Office and the Food and Drug Adminis-*
 25 *tration, what each such agency considers in its re-*

1 *spective review of applications, and how each such*
 2 *agency evaluates those applications, which may be*
 3 *undertaken through routine and ongoing meetings,*
 4 *workshops, and training sessions.*

5 *“(2) Sharing information on new approvals of*
 6 *patents, human drugs and biological products, new*
 7 *technologies and prior art (as appropriate on a case-*
 8 *by-case basis), and scientific trends and developments.*

9 *“(3) Establishing a process that requires—*

10 *“(A) the Director to request from the Com-*
 11 *missioner (and the Commissioner to provide to*
 12 *the Director, upon receiving such a request)—*

13 *“(i) appropriate information for use*
 14 *by employees of the Office with responsi-*
 15 *bility to examine patent applications under*
 16 *section 131 (referred to in this section as*
 17 *‘patent examiners’) regarding when certain*
 18 *information relating to a human drug or*
 19 *biological product approval, which may in-*
 20 *clude updates to a label or newly approved*
 21 *indications, is made publicly available, in-*
 22 *cluding when such information is posted on-*
 23 *line; and*

24 *“(ii) appropriate access for patent ex-*
 25 *aminers to relevant sources of product ap-*

1 *plication, approval, patent, and labeling in-*
2 *formation or communications between the*
3 *Food and Drug Administration and the*
4 *human drug or biological product sponsors*
5 *that may not currently be subject to public*
6 *disclosure, as appropriate and only to the*
7 *extent necessary for the Office to carry out*
8 *the responsibilities of the Office, such as en-*
9 *sureing accurate representations and access*
10 *to information on whether the claimed in-*
11 *vention that would be the subject of the pat-*
12 *ent was on sale before the effective filing*
13 *date of the claimed invention, as described*
14 *in section 102(a)(1); and*

15 *“(B) the Office to assist the Food and Drug*
16 *Administration in its ministerial role of listing*
17 *appropriate and accurate descriptions of patents.*

18 *“(4) Establishing a process to ensure that, in ap-*
19 *propriate circumstances, at the request of the Direc-*
20 *tor, the Commissioner shall consult with or otherwise*
21 *furnish specific, available information to the Office*
22 *with respect to certain applications, responses, or affi-*
23 *davits after rejections in order to assist patent exam-*
24 *iners in carrying out the duties of those patent exam-*
25 *iners.*

1 “(e) *RULE OF CONSTRUCTION.*—Nothing in subsection
2 (d)(3)(B) shall be construed as—

3 “(1) *directing the Office to interfere with, delay,*
4 *or supersede the ministerial function of the Food and*
5 *Drug Administration of listing patents; or*

6 “(2) *indicating the position of the Office regard-*
7 *ing the ability to assert a patent in infringement liti-*
8 *gation.*

9 “(f) *CONFIDENTIALITY.*—

10 “(1) *IN GENERAL.*—With respect to any record
11 *or other information of the Food and Drug Adminis-*
12 *tration or the Office that is confidential, either such*
13 *agency may share any such information with the*
14 *other agency in furtherance of the activities described*
15 *in this section, which shall remain subject to such*
16 *protections as if the information were held by the*
17 *Food and Drug Administration.*

18 “(2) *PROTOCOLS.*—

19 “(A) *IN GENERAL.*—The task force shall es-
20 *tablish appropriate protocols to safeguard con-*
21 *fidentiality and prevent the inappropriate dis-*
22 *closure of information when sharing information*
23 *between the Office and the Food and Drug Ad-*
24 *ministration.*

1 “(B) *CONTENTS.*—*The protocols established*
2 *under subparagraph (A) shall provide that—*

3 “(i) *before sharing any information de-*
4 *scribed in paragraph (1), the sponsor of the*
5 *human drug or biological product to which*
6 *that information relates shall be provided*
7 *notice of that sharing by the applicable*
8 *agency and with a period of 30 days to con-*
9 *sult with the agency sharing that informa-*
10 *tion; and*

11 “(ii) *the Director shall, in order to*
12 *protect against the inadvertent disclosure of*
13 *information, maintain any information*
14 *shared with the Director by the Commis-*
15 *sioner separate from pending patent appli-*
16 *cations and establish procedures for the*
17 *identification of confidential information.*

18 “(C) *POTENTIAL REMEDIES.*—*In estab-*
19 *lishing protocols under this paragraph, the task*
20 *force shall identify appropriate remedies for any*
21 *potential injury suffered when confidential infor-*
22 *mation is made available, including inadvert-*
23 *ently, through the sharing of information de-*
24 *scribed in this subsection.*

1 “(3) *RULE OF CONSTRUCTION.*—*Nothing in this*
2 *subsection may be construed as superseding any other*
3 *remedy available for the unauthorized disclosure of*
4 *confidential information.*”.

5 (b) *TECHNICAL AND CONFORMING AMENDMENT.*—*The*
6 *table of sections for chapter 1 of title 35, United States*
7 *Code, is amended by adding at the end the following:*

 “15. *Interagency Task Force on Patents.*”.

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

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