# Calendar No. 463

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.

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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]

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# 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.

*Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,*

**SECTION 1. SHORT TITLE.**

This Act may be cited as the ''Interagency Patent Coordination and Improvement Act of 2022''.

**SEC. 2. FINDINGS.**

Congress finds the following:

(1) Decisions by the United States Patent and Trademark Office relating to patents may implicate, or have relevance to, information housed at or involving other Federal agencies.

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

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

(4) The Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office is encouraged to work with other Federal agencies.

**SEC. 3. REPORT BY UNITED STATES PATENT AND TRADEMARK OFFICE.**

Not later than 4 years after the date of enactment of this Act, the Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office shall submit to the Committee on the Judiciary of the Senate and the Committee on the Judiciary of the House of Representatives a report that contains—

(1) a description of the frequency with which—

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

(B) the information described in subparagraph (A) is used in patent examinations;

(2) an identification of which methods of providing information, as described in paragraph (1)(A), and types of information so shared, are most useful to patent examiners;

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

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

(4) an identification of other Federal agencies with which the Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office should explore opportunities for coordination that are similar to those undertaken with the Food and Drug Administration through the activities of the Task Force described in paragraph (1)(A).

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

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

(1) in section 2(c), by adding at the end the following:

"(6)(A) In exercising the Director's powers and duties under this section relating to patents, and decisions or actions involving patents, for human drugs and biological products, the Director shall, through the Interagency Task Force on Patents established under section 15, consult with the Commissioner of Food and Drugs in the manner described in that section.

"(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

(2) by adding at the end the following:

**''§ 15. Interagency Task Force on Patents**

''(a) ESTABLISHMENT.—There is established an interagency task force, to be known as the Interagency Task Force on Patents (referred to in this section as the 'task force'), to coordinate efforts between the Director and the Commissioner of Food and Drugs (referred to in this section as the 'Commissioner') regarding communication about, evaluation of, and effective implementation of the activities of the Office and the Food and Drug Administration with respect to patents, and decisions or actions involving patents (as defined in section 2(c)(6)(B)), for human drugs and biological products.

''(b) MEMORANDUM OF UNDERSTANDING.—The Director and the Commissioner shall enter into a memorandum of understanding, or update an existing memorandum of understanding, for the purposes of implementing and carrying out the duties of the task force.

''(c) MEMBERSHIP.—The task force shall be comprised of employees of the Office, who shall be appointed by the Director, and employees of the Food and Drug Administration, who shall be appointed by the Commissioner, who have appropriate expertise and decision-making au-

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

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

"(1) Sharing information on the general processes of the Office and the Food and Drug Administration, what each such agency considers in its respective review of applications, and how each such agency evaluates those applications, which may be undertaken through routine and ongoing meetings, workshops, and training sessions.

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

"(3) Establishing a process that requires—

"(A) the Director to request from the Commissioner (and the Commissioner to provide to the Director, upon receiving such a request)—

"(i) appropriate information for use 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-

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

''(B) the Office to assist the Food and Drug Administration in its ministerial role of listing appropriate and accurate descriptions of patents.

''(4) Establishing a process to ensure that, in appropriate circumstances, at the request of the Director, the Commissioner shall consult with or otherwise furnish specific, available information to the Office with respect to certain applications, responses, or affidavits after rejections in order to assist patent examiners in carrying out the duties of those patent examiners.

''(e) RULE OF CONSTRUCTION.—Nothing in subsection (d)(3)(B) shall be construed as—

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

''(2) indicating the position of the Office regarding the ability to assert a patent in infringement litigation.

''(f) CONFIDENTIALITY.—

''(1) IN GENERAL.—The task force shall establish appropriate protocols to safeguard confiden-

~~tiality and prevent the inappropriate disclosure of information when sharing information between the Office and the Food and Drug Administration.~~

~~"(2) POTENTIAL REMEDIES.—In establishing protocols under paragraph (1), the task force shall identify appropriate remedies for any potential injury suffered when confidential information is made available, including inadvertently, through the sharing of information described in that paragraph.".~~

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

~~"15. Interagency Task Force on Patents.".~~

~~(c) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to the Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office and the Commissioner of Food and Drugs such sums as may be necessary for the purposes of carrying out the functions of the Interagency Task Force on Patents established under section 15 of title 35, United States Code, as added by subsection (a).~~

***SECTION 1. SHORT TITLE.***

*This Act may be cited as the "Interagency Patent Coordination and Improvement Act of 2022".*

***SEC. 2. FINDINGS.***

*Congress finds the following:*

*(1) Decisions by the United States Patent and Trademark Office relating to patents may implicate, or have relevance to, information housed at or involving other Federal agencies.*

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

*(3) Research has shown that patent examiners may benefit from additional information that is housed at, or is available to, Federal agencies other than the United States Patent and Trademark Office in order to assess prior art and the state of science and technology.*

*(4) The Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office is encouraged to work with other Federal agencies.*

***SEC. 3. REPORT BY UNITED STATES PATENT AND TRADEMARK OFFICE.***

*Not later than 4 years after the date of enactment of this Act, the Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and*

*Trademark Office shall submit to the Committee on the Judiciary of the Senate and the Committee on the Judiciary of the House of Representatives a report that contains—*

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

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

*(B) the information described in subparagraph (A) is used in patent examinations;*

*(2) an identification of which methods of providing information, as described in paragraph (1)(A), and types of information so shared, are most useful to patent examiners;*

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

*(4) an identification of other Federal agencies with which the Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office should explore opportunities for coordination that are similar to those un-*

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

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

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

*(1) in section 2(c), by adding at the end the following:*

*"(6)(A) In exercising the Director's powers and duties under this section relating to patents, and decisions or actions involving patents, for human drugs and biological products, the Director shall, through the Interagency Task Force on Patents established under section 15, consult with the Commissioner of Food and Drugs in the manner described in that section.*

*"(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*

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

***"§ 15. Interagency Task Force on Patents***

*"(a) ESTABLISHMENT.—There is established an interagency task force, to be known as the Interagency Task Force on Patents (referred to in this section as the 'task force'), to coordinate efforts between the Director and the Commissioner of Food and Drugs (referred to in this section*

*as the 'Commissioner') regarding communication about, evaluation of, and effective implementation of the activities of the Office and the Food and Drug Administration with respect to patents, and decisions or actions involving patents (as defined in section 2(c)(6)(B)), for human drugs and biological products.*

*"(b) MEMORANDUM OF UNDERSTANDING.—The Director and the Commissioner shall enter into a memorandum of understanding, or update an existing memorandum of understanding, for the purposes of implementing and carrying out the duties of the task force.*

*"(c) MEMBERSHIP.—The task force shall be comprised of employees of the Office, who shall be appointed by the Director, and employees of the Food and Drug Administration, who shall be appointed by the Commissioner, who have appropriate expertise and decision-making authority regarding operational, administrative, technical, medical, pharmacological, clinical, and scientific matters to carry out the functions of the task force.*

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

*"(1) Sharing information on the general processes of the Office and the Food and Drug Administration, what each such agency considers in its re-*

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

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

*"(3) Establishing a process that requires—*

*"(A) the Director to request from the Commissioner (and the Commissioner to provide to the Director, upon receiving such a request)—*

*"(i) appropriate information for use by employees of the Office with responsibility 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 ap-*

*plication, approval, patent, and labeling information or communications between the Food and Drug Administration and the human 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, such as ensuring accurate representations and access to information on whether the claimed invention that would be the subject of the patent was on sale before the effective filing date of the claimed invention, as described in section 102(a)(1); and*

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

*"(4) Establishing a process to ensure that, in appropriate circumstances, at the request of the Director, the Commissioner shall consult with or otherwise furnish specific, available information to the Office with respect to certain applications, responses, or affidavits after rejections in order to assist patent examiners in carrying out the duties of those patent examiners.*

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

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

*"(2) indicating the position of the Office regarding the ability to assert a patent in infringement litigation.*

*"(f) CONFIDENTIALITY.—*

*"(1) IN GENERAL.—With respect to any record or other information of the Food and Drug Administration or the Office that is confidential, either such agency may share any such information with the other agency in furtherance of the activities described in this section, which shall remain subject to such protections as if the information were held by the Food and Drug Administration.*

*"(2) PROTOCOLS.—*

*"(A) IN GENERAL.—The task force shall establish appropriate protocols to safeguard confidentiality and prevent the inappropriate disclosure of information when sharing information between the Office and the Food and Drug Administration.*

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

*"(i) before sharing any information described in paragraph (1), the sponsor of the human drug or biological product to which that information relates shall be provided notice of that sharing by the applicable agency and with a period of 30 days to consult with the agency sharing that information; and*

*"(ii) the Director shall, in order to protect against the inadvertent disclosure of information, maintain any information shared with the Director by the Commissioner separate from pending patent applications and establish procedures for the identification of confidential information.*

*"(C) POTENTIAL REMEDIES.—In establishing protocols under this paragraph, the task force shall identify appropriate remedies for any potential injury suffered when confidential information is made available, including inadvertently, through the sharing of information described in this subsection.*

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

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

*"15. Interagency Task Force on Patents.".*

*(c) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to the Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office and the Commissioner of Food and Drugs such sums as may be necessary for the purposes of carrying out the functions of the Interagency Task Force on Patents established under section 15 of title 35, United States Code, as added by subsection (a).*

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