

NYIPLA
PTAB COMMITTEE
December 7, 2021



Pending IP Legislation: What You
Need to Know

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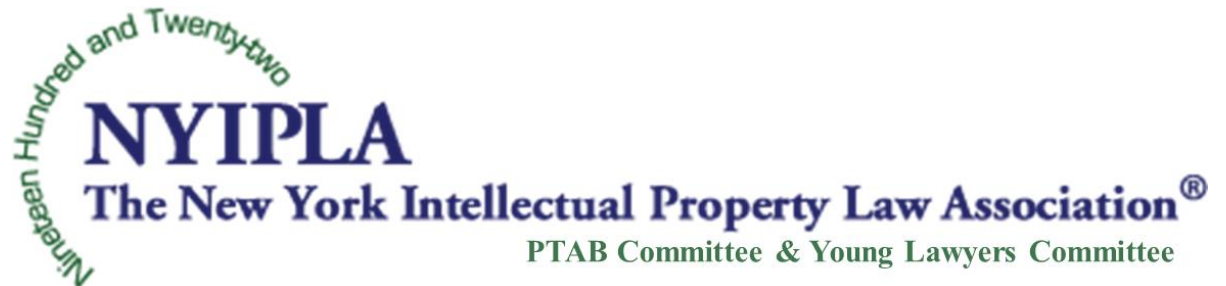


Patent
Trial And
Appeal
Board

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Additionally, the following content is presented solely for the purposes of discussion and illustration, and does not comprise, nor is to be considered, as legal advice.



The Legislation in the Hopper

Rep. Issa et al. introduce a bill (H.R. 3664) on exempting car components from patent infringement

1 June 2021

Sens. Leahy & Tillis introduce two bills (S.2273: Unleashing American Innovators Act of 2021; and S.2274: Pride in Patent Ownership Act)

21 Sep.
2021

Sens. Leahy & Cornyn introduced a bill (S.2891: Restoring the American Invents Act)

29 Sep.
2021

Rep. Masse et al. introduce a bill (H.R. 5874 – Restoring America’s Leadership in Innovation Act) seeking to undue AIA

4 Nov.
2021

Rep. Issa introduces a bill (H.R. 5902, CARES Patent Act of 2021) relating to IPR, Pos—Grant and other administrative proceedings

5 Nov.
2021

The Senate



**S.2891 – Restoring the
American Invents Act
117th Congress
(2021-2022)**

Sponsors:

Sen. Leahy (D-VT)
Sen. Cornyn (R-TX)
Sen. Crapo (R-ID)
Sen. Klobuchar (D-MN)
Sen. Blumenthal (D-CT)

Available at:

<https://www.congress.gov/bill/117th-congress/senate-bill/2891>

117TH CONGRESS
1ST SESSION

S. 2891

To amend title 35, United States Code, to address matters relating to the Patent Trial and Appeal Board of the United States Patent and Trademark Office, and for other purposes.

IN THE SENATE OF THE UNITED STATES

SEPTEMBER 29, 2021

Mr. LEAHY (for himself and Mr. CORNYN) 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 address matters relating to the Patent Trial and Appeal Board of the United States Patent and Trademark Office, and for other purposes.

S.2891 – Restoring the America Invents Act

117th Congress (2021-2022)

To amend title 35, United States Code, to address matters relating to the Patent Trial and Appeal Board of the United States Patent and Trademark Office, and for other purposes.

Fixing *Arthrex* Issue By Adding in Director Review and appointment by Secretary to Section 6 of the Patent Act

35 U.S.C. Sec 6 – Patent Trial and Appeals Board

(c) 3-Member Panels.—Each appeal, derivation proceeding, post-grant review, and inter partes review shall be heard by at least 3 members of the Patent Trial and Appeal Board, who shall be designated by the Director. ~~Only the~~ **The** Patent Trial and Appeal Board may grant rehearings. **After the constitution of a panel of the Patent Trial and Appeal Board under this subsection has been made public, any changes to the constitution of that panel shall be noted in the record.**

(d) [New REVIEW BY DIRECTOR SECTION]

(~~d~~e) Treatment of Prior Appointments.—The Secretary of Commerce may, in the Secretary’s discretion, deem the appointment of an administrative patent judge who, before the date of the enactment ~~of this subsection~~ **of the Restoring the American Invents Act**, held office pursuant to an appointment by the Director **or the Secretary** to take effect on the date on which the Director **or the Secretary, as applicable**, initially appointed the administrative patent judge. It shall be a defense to a challenge to the appointment of an administrative patent judge on the basis of the judge’s having been originally appointed by the Director, **or before the date of enactment of the Restoring the America Invents Act, having performed duties no longer performed by the administrative patent judges**, that the administrative patent judge so appointed **that the applicable administrative patent judge** was acting as a de facto officer.

S.2891 – Restoring the America Invents Act

117th Congress (2021-2022)

To amend title 35, United States Code, to address matters relating to the Patent Trial and Appeal Board of the United States Patent and Trademark Office, and for other purposes.

New Director Review to Section 6(d) of the Patent Act

(d) **Review By Director.**—

(1) **IN GENERAL.**—With respect to a final decision of the Patent Trial and Appeal Board—

(A) the Director may, on the initiative of the Director, review, and modify or set aside, the decision; and

(B) if the decision is issued under section 318 or 328, a party to the applicable inter partes or post-grant review may request that the Director review, and modify or set aside, the decision.

(2) **REQUIREMENT.**—Any review by the Director under paragraph (1) shall be issued in a separate written opinion that—

(A) is made part of the public record; and

(B) sets forth the reasons for the review, modification, or setting aside of the final decision of the Patent Trial and Appeal Board.

(3) **TIMELINE AND BASES FOR REVIEW.**—Not later than 18 months after the date of enactment of the Restoring the America Invents Act, the Director shall promulgate rules addressing the following issues:

(A) With respect to review of a decision on the initiative of the Director under paragraph (1)(A)—

(i) the timeline under which the Director may review the decision, which shall be consistent with the requirements under section 318(e) or 328(e), if applicable; and

(ii) the bases on which the Director may review the decision.

(B) With respect to a request by a party under paragraph (1)(B)—

(i) the timeline for submitting such a request;

(ii) the content that the party is required to include in such a request;

(iii) the bases on which the party may submit such a request; and

(iv) the timeline for any response or reply to such a request such that the request can be decided within the deadline imposed under section 318(e) or 328(e), as applicable.

(4) **RULE OF CONSTRUCTION.**—For the purposes of an appeal permitted under section 141, any decision on review issued by the Director under this subsection shall be deemed a final decision of the Patent Trial and Appeal Board.

S.2891 – Restoring the America Invents Act

117th Congress (2021-2022)

To amend title 35, United States Code, to address matters relating to the Patent Trial and Appeal Board of the United States Patent and Trademark Office, and for other purposes.

New Director Review to Section 6(d) of the Patent Act

35 U.S.C. Sec 318 –Decision of the Board

(a)FINAL WRITTEN DECISION.—

If an inter partes review is instituted and not dismissed under this chapter, the Patent Trial and Appeal Board shall issue a final written decision with respect to the patentability of any patent claim challenged by the petitioner and any new claim added under section 316(d).

(b)CERTIFICATE.—

If the Patent Trial and Appeal Board issues a final written decision under subsection (a) and the time for appeal has expired or any appeal has terminated, the Director shall, **not later than 60 days after the date on which the parties to the inter partes review have informed the Director that the time for appeal has expired or any appeal has terminated** issue and publish a certificate canceling any claim of the patent finally determined to be unpatentable, confirming any claim of the patent determined to be patentable, and incorporating in the patent by operation of the certificate any new or amended claim determined to be patentable.

(c)INTERVENING RIGHTS.—

Any proposed amended or new claim determined to be patentable and incorporated into a patent following an inter partes review under this chapter shall have the same effect as that specified in section 252 for reissued patents on the right of any person who made, purchased, or used within the United States, or imported into the United States, anything patented by such proposed amended or new claim, or who made substantial preparation therefor, before the issuance of a certificate under subsection (b).

S.2891 – Restoring the America Invents Act 117th Congress (2021-2022)

To amend title 35, United States Code, to address matters relating to the Patent Trial and Appeal Board of the United States Patent and Trademark Office, and for other purposes.

New Director Review to Section 6(d) of the Patent Act

35 U.S.C. Sec 318 –Decision of the Board

(d) DATA ON LENGTH OF REVIEW.—

The Office shall make available to the public data describing the length of time between the institution of, and the issuance of a final written decision under subsection (a) for, each inter partes review.

(e) REHEARING.—Not later than 120 days after the date on which the Patent Trial and Appeal Board issues a final written decision under subsection (a), the Board or the Director shall finally decide any request for reconsideration, rehearing, or review that is submitted with respect to the decision, except that the Director may, for good cause shown, extend that 120-day period by not more than 60 days.

S.2891 – Restoring the America Invents Act 117th Congress (2021-2022)

To amend title 35, United States Code, to address matters relating to the Patent Trial and Appeal Board of the United States Patent and Trademark Office, and for other purposes.

Reversing *Return Mail v. USPS*, 139 S.Ct. 1853 (2019) (to make a governmental entity a “person” who can institute a reexam, IPR and/or PGR proceedings)

35 U.S.C. Sec 302 – Request for reexamination

Any person, including a governmental entity, at any time may file a request for reexamination by the Office of any claim of a patent on the basis of any prior art cited under the provisions of section 301. The request must be in writing and must be accompanied by payment of a reexamination fee established by the Director pursuant to the provisions of section 41. The request must set forth the pertinency and manner of applying cited prior art to every claim for which reexamination is requested. Unless the requesting person is the owner of the patent, the Director promptly will send a copy of the request to the owner of record of the patent.

35 U.S.C. Sec 311 – Inter partes review

(a) In General.—Subject to the provisions of this chapter, a person, including a governmental entity, who is not the owner of a patent may file with the Office a petition to institute an inter partes review of the patent. The Director shall establish, by regulation, fees to be paid by the person requesting the review, in such amounts as the Director determines to be reasonable, considering the aggregate costs of the review.

35 U.S.C. Sec 321 – Post-grant review

(a) In General.—Subject to the provisions of this chapter, a person, including a governmental entity, who is not the owner of a patent may file with the Office a petition to institute a post-grant review of the patent. The Director shall establish, by regulation, fees to be paid by the person requesting the review, in such amounts as the Director determines to be reasonable, considering the aggregate costs of the post-grant review.

S.2891 – Restoring the America Invents Act

117th Congress (2021-2022)

To amend title 35, United States Code, to address matters relating to the Patent Trial and Appeal Board of the United States Patent and Trademark Office, and for other purposes.

Expanding the scope of IPR reviews to include admitted prior art in the patent, and double patenting.

35 U.S.C. Sec 311 – Inter partes review

(b)Scope.—A petitioner in an inter partes review may request to cancel as unpatentable 1 or more claims of a patent only on a ground that could be raised ~~under section 102 or 103 and only on the basis of prior art consisting of patents or printed publications.~~ under—

(1) section 102 or 103 and only on the basis of—

(A) prior art consisting of patents or printed publications; or

(B) admissions in the patent specification, drawings, or claims; or

(2) statutory or obviousness-type double patenting on the basis of—

(A) patents or printed publications; or

(B) admissions in the patent specification, drawings, or claims.

S.2891 – Restoring the America Invents Act

117th Congress (2021-2022)

To amend title 35, United States Code, to address matters relating to the Patent Trial and Appeal Board of the United States Patent and Trademark Office, and for other purposes.

Reversing *Fintiv* et al. re: discretionary denials and expanding *Click-to-Call*

35 U.S.C. Sec 314 – Institution of inter partes review

(a) Threshold.—~~The Director may not authorize an inter partes review to be instituted unless~~ **Subject only to the discretion of the Director under 325(d)(4), a petition that meets the requirements of this chapter shall be instituted if** the Director determines that the information presented in the petition filed under section 311 and any response filed under section 313 shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.

(b) Timing.—The Director shall determine whether to institute an inter partes review under this chapter pursuant to a petition filed under section 311 within 3 months after—

(1) receiving a preliminary response to the petition under section 313; or

(2) if no such preliminary response is filed, the last date on which such response may be filed.

(c) Notice.—The Director shall notify the petitioner and patent owner, in writing, of the Director’s determination under subsection (a), and shall make such notice available to the public as soon as is practicable. Such notice shall include the date on which the review shall commence.

(d) No Appeal.—The determination by the Director whether to institute **or maintain** an inter partes review under this ~~section~~ **chapter** shall be final and nonappealable.

S.2891 – Restoring the America Invents Act 117th Congress (2021-2022)

To amend title 35, United States Code, to address matters relating to the Patent Trial and Appeal Board of the United States Patent and Trademark Office, and for other purposes.

Reversing time bar based on action that was dismissed without prejudice.

35 U.S.C. Sec 315 –Relation to other proceedings or actions

(a) Infringer’s Civil Action.—

(1) Inter partes review barred by civil action.—~~An inter partes~~

(A) IN GENERAL – An inter parties review may not be instituted if, before the date on which the petition for such a review is filed, the petitioner or real party in interest filed a civil action challenging the validity of a claim of the patent.

(B) RULE OF CONSTRUCTION. – Subparagraph (A) may not be construed to prevent an inter partes review from being instituted in a complaint in a civil action described in that subparagraph has been dismissed without prejudice.

(2) **Stay of civil action.**—If the petitioner or real party in interest files a civil action challenging the validity of a claim of the patent on or after the date on which the petitioner files a petition for inter partes review of the patent, that civil action shall be automatically stayed until either—

(A) the patent owner moves the court to lift the stay;

(B) the patent owner files a civil action or counterclaim alleging that the petitioner or real party in interest has infringed the patent; or

(C) the petitioner or real party in interest moves the court to dismiss the civil action.

(3) **Treatment of counterclaim.**—A counterclaim challenging the validity of a claim of a patent does not constitute a civil action challenging the validity of a claim of a patent for purposes of this subsection.

could have raised during that inter partes review.

S.2891 – Restoring the America Invents Act

117th Congress (2021-2022)

To amend title 35, United States Code, to address matters relating to the Patent Trial and Appeal Board of the United States Patent and Trademark Office, and for other purposes.

Limiting scope of 1-year bar, for request for joinders, dismissals without prejudice, or new or amended claims

35 U.S.C. Sec 315 –Relation to other proceedings or actions

~~**(b) Patent Owner's Action.**—An inter partes review may not be instituted if the petition requesting the proceeding is filed more than 1 year after the date on which the petitioner, real party in interest, or privy of the petitioner is served with a complaint alleging infringement of the patent. The time limitation set forth in the preceding sentence shall not apply to a request for joinder under subsection (c).~~

(b) Patent Owner's Action.—

(1) IN GENERAL.—An inter partes review may not be instituted if the petition requesting the proceeding is filed more than 1 year after the date on which the petitioner, real party in interest, or privy of the petitioner is served with a complaint alleging infringement of the patent. The time limitation set forth in the preceding sentence shall be subject to the following limitations:

(A) The time limitation shall not apply—

(i) to a request for joinder under subsection (c); or

(ii) if the complaint is dismissed without prejudice.

(B) If new or amended claims issue from reexamination after the petitioner, real party in interest, or privy of the petitioner is served with the complaint, an inter partes review of those claims may be instituted if the petition requesting the review is filed not later than 1 year after the date on which the challenged claims are asserted in the action.

S.2891 – Restoring the America Invents Act

117th Congress (2021-2022)

To amend title 35, United States Code, to address matters relating to the Patent Trial and Appeal Board of the United States Patent and Trademark Office, and for other purposes.

Limiting Grounds for denying stays pending IPR and providing for interlocutory appeals.

35 U.S.C. Sec 315 –Relation to other proceedings or actions

(b) Patent Owner’s Action.—

(2) REQUEST FOR STAY.—

(A) IN GENERAL.—If a party seeks a stay of a civil action brought under section 281 alleging infringement of a patent that is also subject to an inter partes review, the court shall decide whether to stay the civil action based on whether—

(i) the outcome of the inter partes review will likely simplify the issues in question in the civil action and streamline the proceedings in the civil action;

(ii) as of the date on which the stay is requested, discovery in the civil action is complete;

(iii) a stay, or the denial thereof, would—

(I) unduly prejudice the nonmoving party; or

(II) present a clear tactical advantage for the moving party; and

(iv) a stay, or the denial thereof, will reduce the burden of litigation on the parties to the civil action and the court.

(B) REVIEW.—A party may take an immediate interlocutory appeal from the decision of a district court of the United States under subparagraph (A). The United States Court of Appeals for the Federal Circuit shall review the district court’s decision to ensure consistent application of established precedent, and such review shall be de novo.

S.2891 – Restoring the America Invents Act 117th Congress (2021-2022)

To amend title 35, United States Code, to address matters relating to the Patent Trial and Appeal Board of the United States Patent and Trademark Office, and for other purposes.

Reversing *Fintiv* et al. re: discretionary denials and expanding *Click-to-Call*

35 U.S.C. Sec 315 –Relation to other proceedings or actions

(c) Joinder.—~~If the Director~~

(1) IN GENERAL.—**If the Director** institutes an inter partes review, the Director, in his or her discretion, may join as a party to that inter partes review any person who properly files a petition under section 311 that the Director, after receiving a preliminary response under section 313 or the expiration of the time for filing such a response, determines warrants the institution of an inter partes review under section 314.

(2) ESTOPPEL.—**Any person joined as a party to an inter partes review, and any real party in interest or privy of such person, shall be estopped under subsection (e) to the same extent as if that person, real party in interest, or privy had been the first petitioner in that inter partes review.**

S.2891 – Restoring the America Invents Act

117th Congress (2021-2022)

To amend title 35, United States Code, to address matters relating to the Patent Trial and Appeal Board of the United States Patent and Trademark Office, and for other purposes.

Reversing *Fintiv* et al. re: discretionary denials and expanding *Click-to-Call*

35 U.S.C. Sec 315 –Relation to other proceedings or actions

~~(d) Multiple Proceedings.—Notwithstanding sections 135(a), 251, and 252, and chapter 30, during the pendency of an inter partes review, if another proceeding or matter involving the patent is before the Office, the Director may determine the manner in which the inter partes review or other proceeding or matter may proceed, including providing for stay, transfer, consolidation, or termination of any such matter or proceeding.~~

(d) Multiple Proceedings.—

(1) IN GENERAL.—Notwithstanding sections 135(a), 251, and 252, and chapter 30, during the pendency of an inter partes review, if another proceeding or matter involving the patent is before the Office, or if there is a pending application claiming the benefit of a common filing date to the patent under section 120 or 121—

(A) the parties shall notify the Director; and

(B) the Director shall issue a decision determining the manner in which the other proceeding or matter may proceed, including providing for stay, transfer, consolidation, or termination of any such proceeding or matter.

(2) NO EXTENSION.—A decision of the Director under paragraph (1)(B) may not—

(A) extend any statutory deadline under this chapter; or

(B) terminate an inter partes proceeding in favor of an ex parte proceeding.

(3) PRESUMPTION.—For the purposes of this subsection, if the multiple proceedings described in paragraph (1) are of like type and are filed reasonably close in time, there shall be a rebuttable presumption that the Director shall consolidate the proceedings under that paragraph.

S.2891 – Restoring the America Invents Act

117th Congress (2021-2022)

To amend title 35, United States Code, to address matters relating to the Patent Trial and Appeal Board of the United States Patent and Trademark Office, and for other purposes.

Expanding Estoppel Effect against Patent Owner

35 U.S.C. Sec 315 –Relation to other proceedings or actions

(e) Estoppel.—

(1) Proceedings before the office.—~~The petitioner in~~

(A) ESTOPPEL AGAINST PETITIONER.—The petitioner in an inter partes review of a claim in a patent under this chapter that results in a final written decision under section 318(a), or the real party in interest or privy of the petitioner, may not, **after the time for appeal of the decision has expired or any such appeal has terminated** request or maintain a proceeding before the Office with respect to that claim on any ground that the petitioner raised or reasonably could have raised during that inter partes review.

(B) ESTOPPEL AGAINST PATENT OWNER.—The Office may not issue to a patent owner any claim that is not patentably distinct from a claim that was issued and was subsequently—

(i) found to be unpatentable; or

(ii) canceled in any proceeding before the Office, including under section 135, 251, 253, 301, 311, or 321.

(2) Civil actions and other proceedings.—The petitioner in an inter partes review of a claim in a patent under this chapter that results in a final written decision under section 318(a) **that the claim is not unpatentable**, or the real party in interest or privy of the petitioner, may not, **after the time for appeal of the decision has expired or any such appeal has terminated**, assert either in a civil action arising in whole or in part under section 1338 **or 1498** of title 28 or in a proceeding before the International Trade Commission under section 337 of the Tariff Act of 1930 that the claim is invalid on any ground that the petitioner raised or reasonably could have raised during that inter partes review.

S.2891 – Restoring the America Invents Act 117th Congress (2021-2022)

To amend title 35, United States Code, to address matters relating to the Patent Trial and Appeal Board of the United States Patent and Trademark Office, and for other purposes.

Authorizing Director to Issue Regulations on Consolidation under Section 315(d)

35 U.S.C. Sec 316 –Conduct of inter partes review

(a)Regulations.—The Director shall prescribe regulations—

(12) setting a time period for requesting joinder under section 315(c) or consolidation under section 315(d); and

S.2891 – Restoring the America Invents Act

117th Congress (2021-2022)

To amend title 35, United States Code, to address matters relating to the Patent Trial and Appeal Board of the United States Patent and Trademark Office, and for other purposes.

Eliminating Influence on Panels from Within the USPTO

35 U.S.C. Sec 316 –Conduct of inter partes review

(c) Patent Trial and Appeal Board.—

(1) IN GENERAL.—The Patent Trial and Appeal Board shall, in accordance with section 6, conduct each inter partes review instituted under this chapter.

(2) EX PARTE COMMUNICATION.—An officer who has review authority, supervisory authority, or disciplinary authority with respect to an administrative patent judge of the Patent Trial and Appeal Board (or a delegate of such an officer), and who is not a member of a panel described in section 6(c), shall refrain from ex parte communication with such a judge who is a member of that panel concerning any pending matter before that panel, except as allowed under the Code of Conduct for United States Judges.

S.2891 – Restoring the America Invents Act 117th Congress (2021-2022)

To amend title 35, United States Code, to address matters relating to the Patent Trial and Appeal Board of the United States Patent and Trademark Office, and for other purposes.

Codifying Evidentiary Standards on Amending Claims

35 U.S.C. Sec 316 –Conduct of inter partes review

(e)Evidentiary Standards.—

~~In an~~

(1) IN GENERAL.—In an inter partes review instituted under this chapter, the petitioner shall have the burden of proving a proposition of unpatentability **of the challenged patent claims** by a preponderance of the evidence.

(2) CLAIM AMENDMENT.—For any substitute claim proposed under subsection (d)—

(A) the patent owner shall have the burden of proving patentability, including under sections 101, 102, 103, and 112, by a preponderance of the evidence;

(B) the Patent Trial and Appeal Board shall—

(i) examine the substitute claim; or

(ii) notwithstanding subsection (c)(2), refer the substitute claim to the Director, who shall cause an examination of the substitute claim to be made within the time limits for the applicable inter partes review; and

(C) the Director may establish, by regulation, fees for examination of the substitute claim in such amounts as the Director determines to be reasonable, taking into consideration the aggregate costs of examination.

S.2891 – Restoring the America Invents Act

117th Congress (2021-2022)

To amend title 35, United States Code, to address matters relating to the Patent Trial and Appeal Board of the United States Patent and Trademark Office, and for other purposes.

Expanding Standing to Appeal by Confirming New Examples of Injury in Fact and Limiting Estoppel if No Standing

35 U.S.C. Sec 319 –Appeal

A party

(a) IN GENERAL.—A party dissatisfied with the final written decision of the Patent Trial and Appeal Board under section 318(a) may appeal the decision pursuant to sections 141 through 144. Any party to the inter partes review shall have the right to be a party to the appeal.

(b) STANDING.—

(1) INJURY IN FACT.—For the purposes of an appeal described in subsection (a), injury in fact shall be presumed if the party appealing the decision—

(A) reasonably expects that another person will assert estoppel against the party under section 315(e) as a result of the final written decision that is the subject of the appeal; or

(B) suffers any other concrete and particularized injury that—

(i) is fairly traceable to the final written decision that is the subject of the appeal; and

(ii) could be redressed through appellate review.

(2) ESTOPPEL.—If a court finds that a party lacks standing to bring an appeal described in subsection (a) under article III of the Constitution of the United States, that party shall not be estopped under section 315(e) with respect to the underlying inter partes review.

CLE CODE

Nineteen Hundred and Twenty-two

NYIPLA

The New York Intellectual Property Law Association®

PTAB Committee

The House of Representatives



**H.R. 2891 – Preserve Access
to Affordable Generics and
Biosimilars Act
117th Congress
(2021-2022)**

Sponsors:

Rep. Nadler, D-NY
Rep. Cicilline, D-RI
Rep. Buck, R-CO
Rep. Maloney, D-NY
Rep. Owens, R-UT
Del. Norton, D-DC-At Large
Rep. Budd, R-NC
Rep. Jackson, D-TX

Available at:

<https://www.congress.gov/bill/117th-congress/house-bill/2891>

117TH CONGRESS
1ST SESSION

H. R. 2891

To prohibit prescription drug companies from compensating other prescription drug companies to delay the entry of a generic drug, biosimilar biological product, or interchangeable biological product into the market.

IN THE HOUSE OF REPRESENTATIVES

APRIL 28, 2021

Mr. NADLER (for himself, Mr. CICILLINE, Mr. BUCK, and Mrs. CAROLYN B. MALONEY of New York) introduced the following bill; which was referred to the Committee on the Judiciary, and in addition to the Committee on Energy and Commerce, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

A BILL

To prohibit prescription drug companies from compensating other prescription drug companies to delay the entry of a generic drug, biosimilar biological product, or interchangeable biological product into the market.

H.R. 2891 – Preserve Access to Affordable Generics and Biosimilars Act 117th Congress (2021-2022)

To prohibit prescription drug companies from compensating other prescription drug companies to delay the entry of a generic drug, biosimilar biological product, or interchangeable biological product into the market.

To provide FTC with authority to stop/limit pay for delay settlements for generic drugs and biosimilars

Bill Summary by CRS

This bill authorizes **the Federal Trade Commission (FTC)** to initiate proceedings against **parties to any agreement resolving or settling a patent infringement claim** in connection with **the sale of a drug or biological product**. Such an agreement is **presumed to have anticompetitive effects** and is a violation of this bill if the **filer of the generic drug or biosimilar application receives anything of value and agrees to limit or forego research, development, manufacturing, marketing, or sales of the generic drug or biosimilar**.

An agreement is **exempted** if the only consideration granted to the generic manufacturer is (1) the right to market its product prior to the expiration of any statutory exclusivity, (2) a payment for reasonable litigation expenses, or (3) a covenant not to sue on any claim that the generic drug or biosimilar infringes a patent. An agreement is also exempt if the agreement's **pro-competitive benefits outweigh the anticompetitive effects**.

When a generic or biosimilar drug manufacturer enters into an agreement with another drug manufacturer related to the manufacturing, marketing, or sale of a drug, the **manufacturers must certify that the material they have given the FTC concerning the agreement contains the complete agreement** and any agreements related to that main agreement, including descriptions of any oral agreements or representations.

The bill imposes **penalties for violations of this bill**, including the **forfeiture of the 180-day marketing exclusivity period** for a generic drug.

<https://www.congress.gov/bill/117th-congress/house-bill/2891>

H.R. 2891 – Preserve Access to Affordable Generics and Biosimilars Act 117th Congress (2021-2022)

To prohibit prescription drug companies from compensating other prescription drug companies to delay the entry of a generic drug, biosimilar biological product, or interchangeable biological product into the market.

To provide FDA with authority to stop/limit pay for delay settlements for generic drugs and biosimilars

The purposes of this Act are—

(1) to enhance competition in the pharmaceutical market by **stopping anticompetitive agreements** between manufacturers of brand name and generic drug products or biosimilar biological products, or among manufacturers of generic drug products or biosimilar biological products, **that limit, delay, or otherwise prevent competition from generic drugs and biosimilar biological products**; and

(2) to support the purpose and intent of antitrust law by **prohibiting anticompetitive practices in the pharmaceutical industry that harm consumers**.

**H.R. 5874 – Restoring
America’s Leadership in
Innovation Act
117th Congress
(2021-2022)**

Sponsors:

Rep. Masse, R-KY;

Rep. Gohmert, R-TX;

Rep. Gosar, R- AZ;

Rep. McClintock, R-CA

Available at:

<https://www.congress.gov/bill/117th-congress/house-bill/5874>

117TH CONGRESS
1ST SESSION

H. R. 5874

To promote the leadership of the United States in global innovation by establishing a robust patent system that restores and protects the right of inventors to own and enforce private property rights in inventions and discoveries, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

NOVEMBER 4, 2021

Mr. MASSIE (for himself, Mr. GOHMERT, Mr. GOSAR, and Mr. MCCLINTOCK) introduced the following bill; which was referred to the Committee on the Judiciary

A BILL

To promote the leadership of the United States in global innovation by establishing a robust patent system that restores and protects the right of inventors to own and enforce private property rights in inventions and discoveries, and for other purposes.

H.R. 5874 – Restoring America’s Leadership in Innovation Act

117th Congress (2021-2022)

To promote the leadership of the United States in global innovation by establishing a robust patent system that restores and protects the right of inventors to own and enforce private property rights in inventions and discoveries, and for other purposes.

Purpose: To repeal the American Invents Act. Congressional Findings:

(1) The Congress created a patent system to “promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries,” as provided for in the Constitution of the United States.

(2) The Leahy-Smith America Invents Act (Public Law 112–29) enacted on September 16, 2011, and several decisions of the Supreme Court have harmed the progress of Science and the useful Arts by eroding the strength and value of the patent system.

(3) The United States Government exists to protect life, liberty, and property, which includes intellectual property.

(4) A United States patent secures a private property right to an inventor.

(5) This Act restores the patent system as envisioned by the Constitution of the United States.

H.R. 5874 – Restoring America’s Leadership in Innovation Act

117th Congress (2021-2022)

To promote the leadership of the United States in global innovation by establishing a robust patent system that restores and protects the right of inventors to own and enforce private property rights in inventions and discoveries, and for other purposes.

Purpose: To repeal the American Invents Act. Congressional Findings:

Sec. 3: Restore the right of the first inventor to secure a patent.

Sec. 4: Abolish inter partes and post-grant review proceeding.

Sec. 5: Abolishing the PTAB and restoring the BPAI.

Sec. 6: Eliminating Fee Diversion and Fully Fund USPTO.

Sec. 7: Revising 101 to limit patent-eligibility exception to exists in nature independent of and prior to any human activity or exists solely in human mind.

Sec. 8: Return 102 & 103 to pre-AIA versions.

Sec. 9: Restoring Patents as Property Right

Sec. 10: Ending Automatic Publication of Patent Applications

Sec. 11: Restoring Presumption of Validity and tolling patent term during Judicial Challenge

Sec. 12: Patent Injunctions – overturning e-Bay

Sec. 13: Restoring Best Mode Requirement

**H.R. 5902 – Conducting Legally
Efficient Administration and
Resolution of Patents Act of
2021
117th Congress
(2021-2022)**

Sponsors:

Rep. Issa, R-CA;

Available at:

<https://www.congress.gov/bill/117th-congress/house-bill/5902>

117TH CONGRESS
1ST SESSION

H. R. 5902

To amend title 35, United States Code, to clarify the relation of Inter Partes Review proceedings and Post-Grant Review proceedings to other administrative proceedings, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

NOVEMBER 5, 2021

Mr. ISSA introduced the following bill; which was referred to the Committee
on the Judiciary

A BILL

To amend title 35, United States Code, to clarify the relation of Inter Partes Review proceedings and Post-Grant Review proceedings to other administrative proceedings, and for other purposes.

H.R. 5902 – Conducting Legally Efficient Administration and Resolution of Patents Act of 2021

117th Congress (2021-2022)

To amend title 35, United States Code, to clarify the relation of Inter Partes Review proceedings and Post-Grant Review proceedings to other administrative proceedings, and for other purposes.

Reversing *Fintiv et al.* re: discretionary denials and expanding *Click-to-Call*

35 U.S.C. Sec 314 – Institution of inter partes review

(f) RELATION TO OTHER ADMINISTRATIVE PROCEEDINGS.—If the Director institutes an inter partes review of a patent, any proceeding before a Federal agency (as that term is defined in section 201) that would be materially affected by one or more of the claims of the patent being cancelled under such review shall be stayed until a final written decision by the Board is issued under such review or such review is otherwise terminated.

35 U.S.C. Sec 325 – Relation to other proceedings or actions

(f) RELATION TO OTHER ADMINISTRATIVE PROCEEDINGS.—If the Director institutes a post-grant review of a patent, any proceeding before a Federal agency (as that term is defined in section 201) that would be materially affected by one or more of the claims of the patent being cancelled shall be stayed until a final written decision by the Board is issued under such review or such re- view is otherwise terminated.

Effective for IPRs and PGRs initiated after enactment and administrative proceedings initiated after 6 months before enactment.

Looking at the
tea leaves --
What else are we
looking forward
to happening at
Congress?



H.R.3666 - STRONGER Patents Act of 2019

116th Congress (2019-2020)

To strengthen the position of the United States as the world's leading innovator by amending title 35, United States Code, to protect the property rights of the inventors that grow the country's economy.

Provides patent owners with greater protection in IPRs, PGRS and with respect to injunctions, but limits bad faith demand letters

Bill Summary by CRS

This bill makes several patent-related changes, including with respect to how the U.S. Patent and Trademark Office (USPTO) conducts administrative patent validity reviews.

When deciding inter partes reviews (IPRs) and post-grant reviews (PGRs), the USPTO's Patent Trial and Appeal Board (PTAB) shall give patent claim terms ***their ordinary and customary meanings*** as understood by a person of ordinary skill in the relevant art (the same standard used in court). If a court has already construed a patent claim, the USPTO shall consider that construction.

The bill makes various changes relating to such proceedings, such as by (1) ***raising the burden of proof to invalidate a patent claim***; (2) establishing that ***a challenged patent claim is presumed valid***; (3) imposing ***standing requirements as to who may file an IPR or PGR***, where none currently exist except for some timing requirements; (4) ***restricting when multiple challenges may be filed against the same patent***; and (5) ***limiting IPRs and PGRs when a court or the International Trade Commission has ruled on the obviousness or novelty of the same patent claims***.

This bill also (1) makes it ***easier to get an injunction after a court finding of the infringement of a valid patent***, by a ***presumption*** that further infringement would cause ***irreparable injury*** and the ***remedies available at law are inadequate***; (2) ***authorizes the USPTO to keep and spend the fees that it collects***; and (3) makes ***bad faith patent demand letters an unfair or deceptive act in violation of the Federal Trade Commission Act***.



President Biden Announces Key Nominations

OCTOBER 26, 2021 • [STATEMENTS AND RELEASES](#)

WASHINGTON – Today, President Joe Biden announced his intent to nominate the following individuals to serve in key roles:

Kathi Vidal, Nominee for Under Secretary for Intellectual Property and Director of the U.S. Patent and Trademark Office at the Department of Commerce

Katherine (“Kathi”) Vidal is one of the leading intellectual property lawyers in the country and has held key leadership and management roles in international law firms. Currently, she is the managing partner of Winston & Strawn’s Silicon Valley Office. Nationally recognized for leading high-profile patent disputes, her experience covers a myriad of complex technologies from semiconductors and software to medical devices and consumer products. Kathi has received numerous accolades for her work— including being inducted as a Fellow by Litigation Counsel of America, a trial lawyer honorary society. Kathi represents both plaintiffs and defendants in U.S. district courts, the International Trade Commission, and at the U.S. Patent and Trademark Office (PTO). Kathi is registered to practice before the PTO and prosecuted many patent applications early in her career. Kathi also advises on IP policies for standard setting organizations, trademark and copyright matters, and on strategies for worldwide patent disputes including advising on national security, policy and related issues. Kathi is also a recognized thought leader on difficult issues confronting the legal profession and intellectual property law, and has been active in the Sedona Conference, the Leahy Institute of Advanced Patent Studies, and the Federal Judicial Conference. She is also a Fellow of the Federal Circuit Bar Association.

Kathi is a recognized leader in diversity and women’s issues. She is one of four law firm advisory board members for CHIPs, a non-profit organization committed to advancing women at the intersection of law, technology, and regulatory policy. She founded the Next Gen initiative and actively advocates for training and opportunities for junior lawyers. She is also a member of Winston & Strawn’s Executive Committee and Diversity. At her prior firm, Fish & Richardson, Kathi was the Litigation Chair and sat on the firm’s management committee. She has a strong technical background, having practiced in industry for five years at General Electric and Lockheed Martin in circuit, systems, software and artificial intelligence. She received her Bachelors and Masters in Electrical Engineering and completed the GE Edison Engineering three-year leadership program. Kathi’s father was a career Navy Senior Chief Officer and her grandparents were scientists at the National Institutes of Health after serving in the Navy.

Questions?



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