

NEW YORK INTELLECTUAL PROPERTY LAW ASSOCIATION

NYIPLA 2021 FALL PATENT CLE
Legislative Developments 2021: Pending and
Proposed Legislation That Would Affect
Intellectual Property Rights
November 16, 2021

Moderator

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Panelists

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NYIPLA 2021 FALL PATENT CLE

Legislative Developments 2021: Pending and Proposed Legislation That Would Affect Intellectual Property Rights

Dana Robert Colarulli

November 16, 2021

Agenda



- Provide some History on the 2011 American Invents Act (AIA) - *goals, process, context*
- Highlight recent “AIA 10-year Anniversary” patent bills
- Make comments on USPTO Director Confirmation Process

Flashback to 2011



Flashback to 2011



September 16, 2011

Flashback to 2011



The slide features the USPTO seal in the top left corner. The title is in a dark blue banner. Below the title, the heading 'Goals of Patent Reform Legislation:' is followed by a bulleted list of five goals. The slide is tilted slightly to the right.

Patent Reform Legislation – “America Invents Act”

Goals of Patent Reform Legislation:

- Encourage innovation and job creation
- Support USPTO's efforts to improve patent quality and reduce backlog
- Establish secure funding mechanism
- Provide greater certainty for patent rights
- Provide less costly, time-limited administrative alternatives to litigation

8

Flashback to 2011



Patent Reform Legislation – “America Invents Act”

Key Provisions of the Act:

- Transition to First-Inventor-to-File
- Provide USPTO Fee-Setting Authority
- Establish Post-Grant and *Inter Partes* Review Procedures
- Post-Grant Review of Business Method Patents
- Supplemental Examination Procedure
- 3rd Party Submissions of Prior Art
- Priority Examination for Important Technologies
- Limits False Marking Litigation
- Expansion of the Existing Prior User Defense

6

Flashback to 2011



Congressional History of Patent Reform Legislation

108th Congress (2003-2004)

- Federal Trade Commission (FTC) and National Academies of Sciences (NAS) Reports issued
- House holds hearings on "Committee Print" (Rep. Smith, April 2004)

109th Congress (2005-2006)

- Senate introduces S.3818 (Sen. Hatch); hearings held
- House introduces H.R.2795 (Rep. Smith); hearings held
- H.R.5096, PDQ Act introduced (Rep. Berman) – *inc. Post Grant, Willfulness, Venue and Injunctions*

110th Congress (2007-2008)

- Senate holds hearings on S.1145; Committee adopts bill but it is never considered on the Floor
- House passes H.R. 1908 (Rep. Berman) on 9/7/2007 by a vote of 220 – 175

111th Congress (2009-2010)

- S.515 and H.R.1260 introduced at Joint Press Conference (March 2009)
- Senate Judiciary Committee Amends and Reports out S.515 (April 2009)
- Administration submits "views letter" supporting much of S.515 (Oct. 2010)

112th Congress (2011-2012)

- S.23 passes the Senate March 8, by a vote of 95-5
- H.R.1249 passes the House June 23 by a vote of 304-117; passes the Senate September 8.
- ***H.R. 1249 Signed into law, September 16, 2011 as Public Law 112-29.***

3

2021 - “AIA 10 year Anniversary” Patent Bills

- [S.2891](#) - **Restoring the America Invents Act**
(Sens. Leahy (D-VT), Cornyn (R-TX), Crapo (R-ID), Klobuchar (D-MN), Blumenthal (D-CT))
- [S.2774](#) - **Pride in Patent Ownership Act**
(Sens. Leahy, D-VT & Tillis, R-NC)
- [S.2773](#) - **Unleashing American Innovators Act of 2021**
(Sens. Leahy, D-VT & Tillis, R-NC)
- **S. ____ - STRONGER Patents Act ([S.2982](#), 116th Congress Version)**
(Sen. Coons, D-DE, expected reintroduction)
- [H.R. 5902](#) – **CLEAR Patents Act**
(Rep. Issa, R-CA)
- [HR 5874](#) - **Restoring America's Leadership in Innovation Act**
(Rep. Masse, R-KY)



2021 - “AIA 10 year Anniversary” Patent Bills (titles only)

- Restoring the America Invents Act
- Pride in Patent Ownership Act
- Unleashing American Innovators Act of 2021
- STRONGER Patents Act -- Support Technology and Research for Our Nation's Growth and Economic Resilience
- CLEAR Patents Act - Conducting Legally Efficient Administration and Resolution
- Restoring America's Leadership in Innovation Act (RALIA)



AIA 10 year “Anniversary Bills” (At-A-Glance)

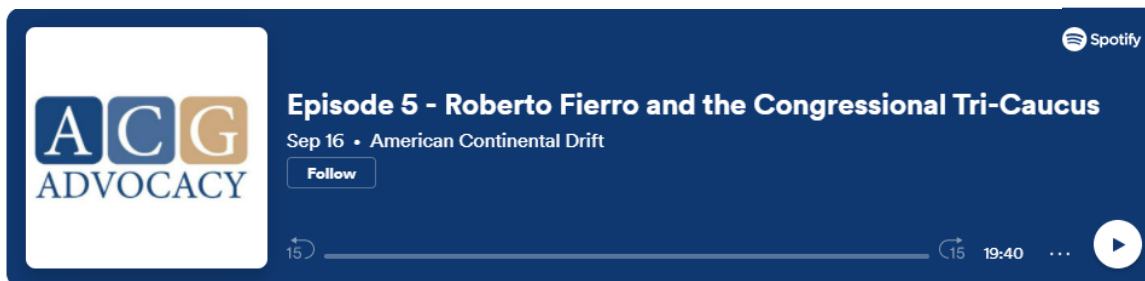


Bill Introduced	Key Issues Addressed
S.2891 - Restoring the America Invents Act (Sens. Leahy (D-VT), Cornyn (R-TX), Crapo (R-ID), Klobuchar (D-MN), Blumenthal (D-CT))	Various PTAB changes; Arthrex fix, rolling back FINTIV factors, other targeted cases overruled (generally pro petitioner)
S.2774 - Pride in Patent Ownership Act (Sens. Leahy, D-VT & Tillis, R-NC)	Transparency; patent assignments
S.2773 - Unleashing American Innovators Act of 2021 (Sens. Leahy, D-VT & Tillis, R-NC)	USPTO Outreach; Creates a new SE Regional USPTO Office; Pro-Bono; Small Entity Fees
S. ____ - STRONGER Patents Act (S.2982, 116th Congress Version) (Sen. Coons, D-DE, expected reintroduction)	Various PTAB Changes; claim construction; burden of proof, standing, limits on serial proceedings, priority of district, composition of IPR panels (generally pro patent owner)
H.R. 5902 – CLEAR Patents Act (Rep. Issa, R-CA)	Coordinating/limiting patent challenges
HR 5874 - Restoring America's Leadership in Innovation Act (Rep. Masse, R-KY)	Returning the US to a First to Invent System (rolling back the AIA provision)

American Continental Drift Podcast

ACG's deep dive into the shifting political landscape of Washington

Current Episode



Other Episodes:

- *Budget Reconciliation (Chris Israel and Sarah Abernathy)*
- *Manus Cooney & Anti-trust*
- *Kris Balderston & ESG*
- *Relationships, Longevity And Horse Racing (Shawn Smeallie)*



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Bayh-Dole Act of 1980

Legislation enacted to clarify rights to federally-funded inventions and to incentivize small businesses and non-profits to collaborate with Federal agencies

- Provided Small Businesses and Non-profits to opportunity to take title to Subject Inventions
- Established a preference for U.S. manufacture of Subject Inventions (waivable by the Agency)
- Afforded funding Agency march-in rights if Subject Inventions were not disclosed or other terms of funding agreement were violated
- Inventions that are not elected for title are licensed pursuant to a revocable license

A Subject Invention is “any invention of the contractor conceived or first actually reduced to practice in the performance of work under a funding agreement”

35 U.S.C. § 201 (e)

Contractors must “disclose each subject invention ... within a reasonable time ... and [the U.S.] may receive title to any subject invention not disclosed to it within such time.”

35 U.S.C. § 202 © (1)

A funding agreement can circumvent Bayh-Dole obligations to small business and non-profits if “in exceptional circumstances when it is determined by the agency that restriction or elimination of the right to retain title to any subject invention will better promote the policy and objectives of [the Act]”

35 U.S.C. § 202 (a) (ii)

Determinations of Exceptional Circumstances

The U.S. Department of Energy has issued 10 Determinations of Exceptional Circumstances since

- Five DEC's in 1981-1985
- In 2000 and 2013, DEC's were issued related to Solid State Energy and Renewable Energy
- Dec. 17, 2019: Cybersecurity, Energy Security and Emergency Response
- Aug. 28, 2020: Quantum Information Science Technologies
- June 6, 2021: To further promote domestic manufacture of DOE science and energy technologies

<https://www.energy.gov/gc/determination-exceptional-circumstances-decs>

Cybersecurity DEC calls for expanded Government license rights and may require Contractors to submit Commercialization and U.S. Manufacturing Plans

Science and Energy Tech. DEC expands QIS DEC terms to all projects under specific Under Secretaries of Science/Energy and ARPA-E

Quantum Information Science DEC requires:

Subject Inventions “will be manufactured substantially in the United States unless ... not commercially feasible.”

Contractor “will not license, assign or otherwise transfer any waived invention to any entity unless that entity agrees to these same requirements.”

Breach and title reverts to the U.S. Government.

Pending Legislation That Would Affect IP Rights

- Patent Settlements
 - Preserve Access to Affordable Generics and Biosimilars Act, H.R. 2891, S. 1428
 - Protecting Consumer Access to Generic Drugs Act of 2021, H.R. 153
- “Product Hopping”
 - Affordable Prescriptions for Patients Through Promoting Competition Act of 2021, H.R. 2873
 - Affordable Prescriptions for Patients Act of 2021, S. 1435 (Sec. 2)
- BPCIA Litigation Limits
 - Affordable Prescriptions for Patients Through Improvements to Patent Litigation Act, H.R. 2884
 - Affordable Prescriptions for Patients Act of 2021, S.1435 (Sec. 3)

Pending along with the following:

- Citizen Petitions
 - Stop Stalling Access to Affordable Medications Act, H.R. 2883
 - Stop STALLING Act, S. 1425

**Legislative Developments 2021: Pending and Proposed Legislation
That Would Affect Intellectual Property Rights**

November 16, 2021

David E. Korn, Vice President, IP and Law, PhRMA

This presentation will discuss legislation currently pending in the House and Senate Judiciary Committees that relates to the exercise of intellectual property rights in the context of biopharmaceuticals. For each, there are versions pending in the House and the Senate. The following list and links are organized by reference to the House version, along with a cross-reference to the Senate counterpart legislation.

Patent Settlements

- “Preserve Access to Affordable Generics and Biosimilars Act,” H.R. 2891, Amendment in the Nature of a Substitute, 117th Cong. (Nadler) [[PDF](#)]
 - Related bill: “Preserve Access to Affordable Generics and Biosimilars Act,” S.1428, 117th Cong. (Klobuchar) [[PDF](#)]
- “Protecting Consumer Access to Generic Drugs Act of 2021,” H.R. 153, 117th Cong. (2021) (Rush) [[PDF](#)]

“Product Hopping”

- “Affordable Prescriptions for Patients Through Promoting Competition Act of 2021,” H.R. 2873, Amendment in the Nature of a Substitute, 117th Cong. (Nadler) [[PDF](#)]
 - Related bill: “Affordable Prescriptions for Patients Act of 2021,” S. 1435 (Sec. 2), 117th Cong. (Cornyn) [[PDF](#)] Amendment in the Nature of a Substitute passed by Senate Judiciary Committee on July 29, 2021

Limits on Litigation Brought under the Biologics Price Competition and Innovation Act (“BPCIA”)

- “Affordable Prescriptions for Patients Through Improvements to Patent Litigation,” H.R. 2884, Amendment in the Nature of a Substitute, 117th Cong. (Johnson) [[PDF](#)]
 - Related bill: “Affordable Prescriptions for Patients Act of 2021,” S.1435 (Sec. 3), 117th Cong. (Cornyn) [[PDF](#)] Amendment in the Nature of a Substitute passed by Senate Judiciary Committee on July 29, 2021

Also pending with this group of bills are the following bills:

Citizen Petitions

- “Stop Stalling Access to Affordable Medications Act,” H.R. 2883, Amendment in the Nature of a Substitute, 117th Cong. (Nadler) [[PDF](#)]
 - Related bill: “Stop STALLING Act,” S. 1425, 117th Cong. (Klobuchar) [[PDF](#)]