October 14, 2015

Post-Grant for Practitioners

Proposed Legislative Changes to IPR—and Their Possible Repercussions

Michael Rosen
Principal

Tom Rozylowicz
Principal

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Agenda

I. Overview of Webinar Series
II. Statistics and challenges
III. Proposed changes to post-grant proceedings
    I. Replacing BRC with “ordinary & customary meaning”
    II. Elevating burden to “clear and convincing”
    III. Legislative status
IV. Exempting life sciences from IPR entirely
    I. Legislative status
    II. CBO score and pushback
V. Assessment
VI. Post-Grant Resources

Overview of Webinar Series

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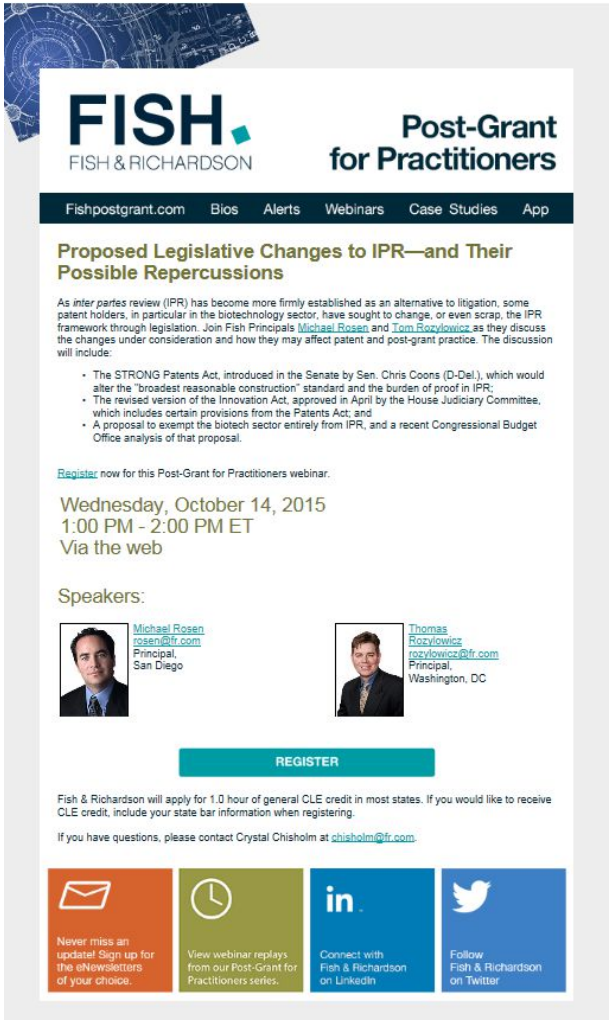
Overview

- Where? … see invitation
- How often? … monthly
- When? … 2nd Wednesday
- Topics? …
  - Important decisions
  - Developments
  - Practice tips
- Housekeeping
  - CLE
  - Questions
  - Materials
    - http://fishpostgrant.com/webinars/



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Post-Grant for Practitioners

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Proposed Legislative Changes to IPR—and Their Possible Repercussions

As *inter partes* review (IPR) has become more firmly established as an alternative to litigation, some patent holders, in particular in the biotechnology sector, have sought to change, or even scrap, the IPR framework through legislation. Join Fish Principals Michael Rosen and Tom Rozylowicz as they discuss the changes under consideration and how they may affect patent and post-grant practice. The discussion will include:

- The STRONG Patents Act, introduced in the Senate by Sen. Chris Coons (D-Del.), which would alter the "broadest reasonable construction" standard and the burden of proof in IPR;
- The revised version of the Innovation Act, approved in April by the House Judiciary Committee, which includes certain provisions from the Patents Act; and
- A proposal to exempt the biotech sector entirely from IPR, and a recent Congressional Budget Office analysis of that proposal.

Register now for this Post-Grant for Practitioners webinar.

Wednesday, October 14, 2015
1:00 PM - 2:00 PM ET
Via the web

Speakers:

Michael Rosen
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Principal,
San Diego

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Principal,
Washington, DC

REGISTER

Fish & Richardson will apply for 1.0 hour of general CLE credit in most states. If you would like to receive CLE credit, include your state bar information when registering.

If you have questions, please contact Crystal Chisholm at chisholm@fr.com.

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Statistics and challenges

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Statistics and challenges

- **IPRs Filed?**
  - **3607** filed through October 9, 2015
  - **136** filed in September 2015
- **CBMs Filed?**
  - **388** filed through October 9, 2015
  - **5** filed in September 2015

Statistics and challenges

- Life sciences IPRs: small fraction of those filed
  - Roughly 10-11% of total number of petitions filed
- But there's been a recent trend of hedge-fund managers filing IPRs against branded drug manufacturers and allegedly selling stocks short
  - Hedge-fund manager Kyle Bass and others have filed petitions against branded pharma companies Shire, Jazz, Celgene, Biogen, Acorda, Pozen, and NPS
  - PTAB has refused to institute proceedings in some of these cases, but it also declined to impose sanctions

Proposed Changes to Post-Grant Proceedings

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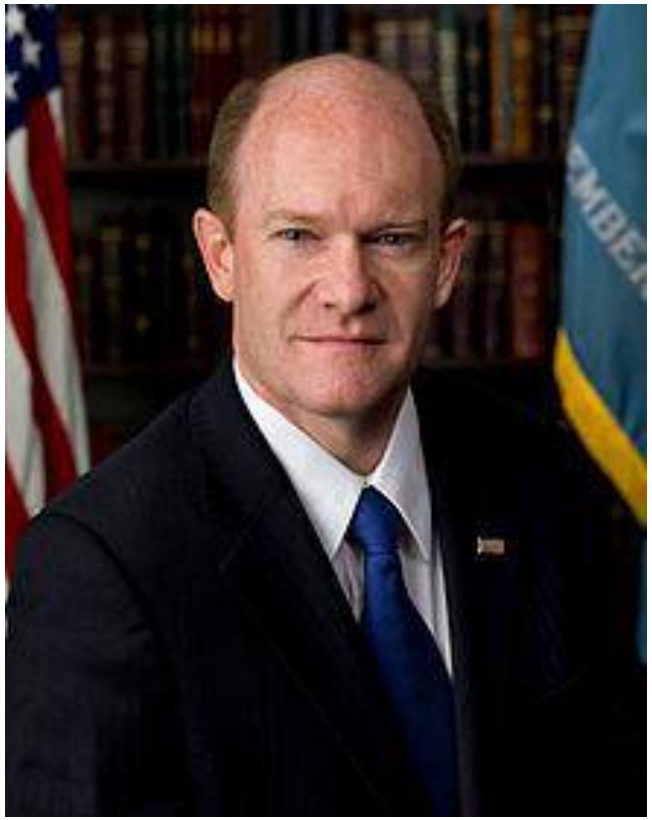
Proposed changes – BRC → ordinary/customary

- Current post-grant standard for all technology: "broadest reasonable construction"
  - Matches old *ex parte* reexam standard
  - Matches examination standard
  - Differs from district court standard of customary and ordinary meaning
- Pro: ensures patents are reviewed under the same standard as examined; broad review of prior art
- Con: inconsistent with district court; makes invalidity challenges too common and too easy

Proposed changes – BRC → ordinary/customary

- In Feb. 2015, Sen. Chris Coons (D-Del.) introduced S. 632 – the STRONG Patents Act
- Laments "unintended consequences of the comprehensive 2011 reform of patent laws," such as "strategic filing of PGR proceedings to depress stock prices and extort settlements."



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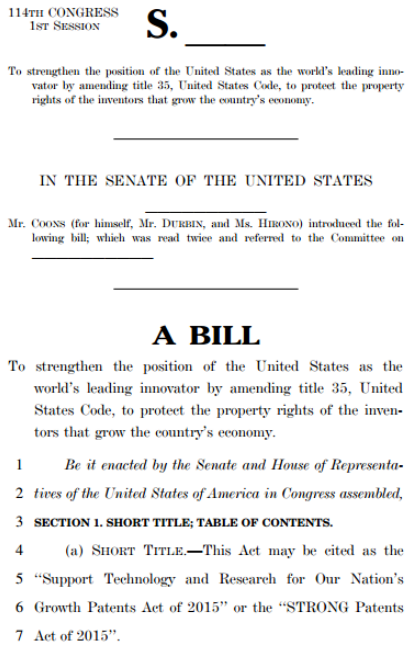
Proposed changes – BRC → ordinary/customary



114TH CONGRESS
1ST SESSION

S. _____

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.

IN THE SENATE OF THE UNITED STATES

Mr. COONS (for himself, Mr. DURBIN, and Ms. HIRONO) introduced the following bill; which was read twice and referred to the Committee on

A BILL

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.

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

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the "Support Technology and Research for Our Nation's Growth Patents Act of 2015" or the "STRONG Patents Act of 2015".

- STRONG Patents Act would change claim construction standard from "broadest reasonable construction" to the "***ordinary and customary meaning*** of the claim as understood by a person having ordinary skill in the art to which the claimed invention pertains"
- Would also make it easier to amend or cancel claims during proceeding

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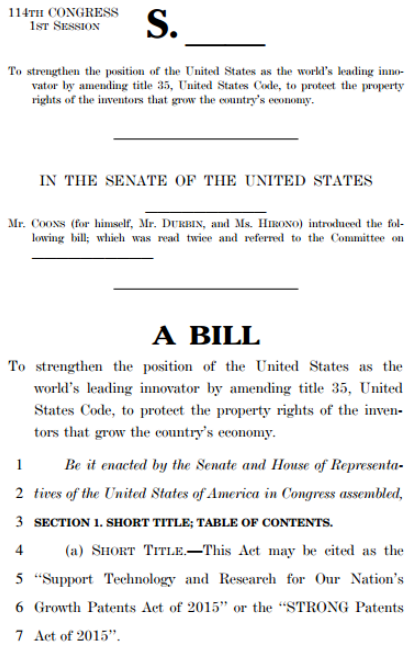
Proposed changes – preponderance → C&C



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- STRONG Patents Act would also elevate the burden of proof from preponderance of the evidence to clear-and-convincing evidence for previously issued claims
- Amended claims would still be subject to a preponderance standard

Proposed changes – legislative status

- Portions introduced into managers' amendment of H.R. 9 – the Innovation Act
  - Introduced in June in House by Judiciary Cmte. Chairman Bob Goodlatte (R-Va.), passed 24-8
- Adopts "ordinary & customary meaning" provision of Coons bill for IPR and PGR

Proposed changes – legislative status

- Also restricts hedge funds
- No institution unless petitioner certifies:
  - (1) that it does not own a "financial instrument . . . designed to hedge or offset any decrease in market value of an equity security of the patent owner or an affiliate" after filing; and
  - (2) that it has not "demanded payment…from the patent owner or an affiliate of the patent owner in exchange for a commitment not to file a petition" (unless the petitioner or any real party in interest has been sued for infringement on the patent)

Proposed changes – legislative status

- Portions introduced into managers' amdmt of S. 1137, the PATENT Act
  - Introduced in June in Senate by Judiciary Cmte. Chairman Charles Grassley (R-Iowa), passed 16-4
- Adopts "ordinary & customary meaning" provision of Coons bill for IPR and PGR
- Vague language regarding "presumption of validity"
- Also empowers PTO director to deny institution if it "would not serve the interests of justice"

Exempting life sciences from IPR entirely

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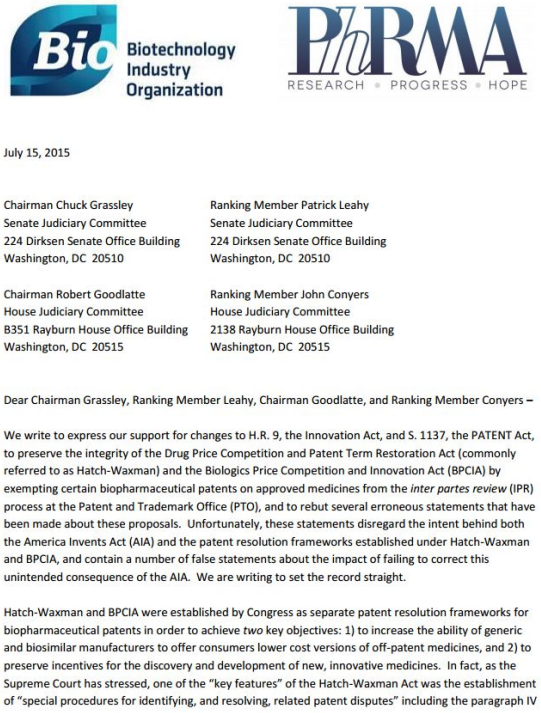
Life sciences exemption – BIO/PhRMA



Bio Biotechnology Industry Organization

PhRMA RESEARCH • PROGRESS • HOPE

July 15, 2015

Chairman Chuck Grassley
Senate Judiciary Committee
224 Dirksen Senate Office Building
Washington, DC 20510

Ranking Member Patrick Leahy
Senate Judiciary Committee
224 Dirksen Senate Office Building
Washington, DC 20510

Chairman Robert Goodlatte
House Judiciary Committee
B351 Rayburn House Office Building
Washington, DC 20515

Ranking Member John Conyers
House Judiciary Committee
2138 Rayburn House Office Building
Washington, DC 20515

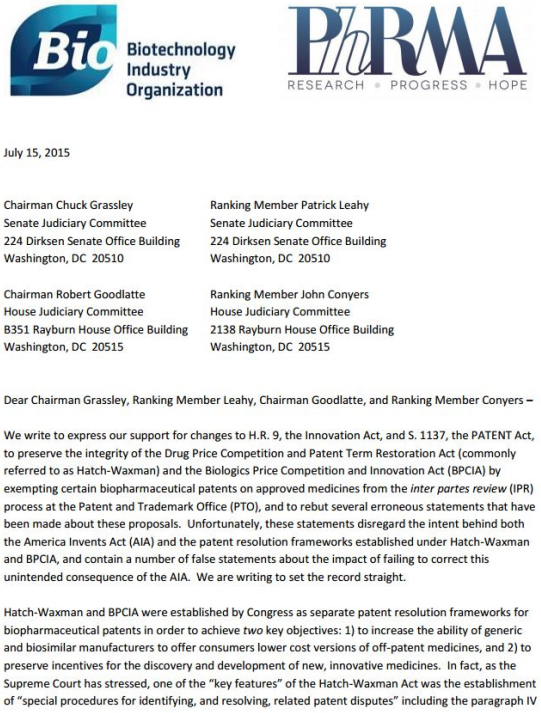
Dear Chairman Grassley, Ranking Member Leahy, Chairman Goodlatte, and Ranking Member Conyers –

We write to express our support for changes to H.R. 9, the Innovation Act, and S. 1137, the PATENT Act, to preserve the integrity of the Drug Price Competition and Patent Term Restoration Act (commonly referred to as Hatch-Waxman) and the Biologics Price Competition and Innovation Act (BPCIA) by exempting certain biopharmaceutical patents on approved medicines from the *inter partes review* (IPR) process at the Patent and Trademark Office (PTO), and to rebut several erroneous statements that have been made about these proposals. Unfortunately, these statements disregard the intent behind both the America Invents Act (AIA) and the patent resolution frameworks established under Hatch-Waxman and BPCIA, and contain a number of false statements about the impact of failing to correct this unintended consequence of the AIA. We are writing to set the record straight.

Hatch-Waxman and BPCIA were established by Congress as separate patent resolution frameworks for biopharmaceutical patents in order to achieve *two* key objectives: 1) to increase the ability of generic and biosimilar manufacturers to offer consumers lower cost versions of off-patent medicines, and 2) to preserve incentives for the discovery and development of new, innovative medicines. In fact, as the Supreme Court has stressed, one of the "key features" of the Hatch-Waxman Act was the establishment of "special procedures for identifying, and resolving, related patent disputes" including the paragraph IV

- In July letter to Congress, the Biotechnology Industry Organization and the Pharmaceutical Research and Manufacturers of America wrote in support of "***exempting certain biopharmaceutical patents*** on approved medicines from the inter partes review (IPR) process at the Patent and Trademark Office (PTO)"

Life sciences exemption – BIO/PhRMA



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- BIO and PhRMA claimed that post-grant proceedings "***threaten[] to disrupt the careful balance*** that Congress achieved over 30 years ago, by ***increasing business uncertainty*** for innovative biopharmaceutical companies having to defend their patents in ***multiple venues and under differing standards and procedures***."

Life sciences exemption – Legislative status

- During June 2015 Judiciary markup of H.R. 9, Rep. Mimi Walters (R-Calif.) introduced amdmt that would have exempted from IPR any “patent that claims a drug or biological product, method of use, or method of mfctrg” approved under Sec. 505 of Food, Drug and Cosmetic Act, including Orange Book patents
- But Rep. Walters withdrew her amendment after Goodlatte opposed it

Life sciences exemption – Congressional Budget Office

- Congressional Budget Office (CBO) charged with "produc[ing] independent analyses of budgetary and economic issues to support the Congressional budget process"
- *Wall St. Journal* reported that, in July, CBO reviewed a proposal to exempt life sciences tech from IPR and found it would increase federal spending by $1.3 billion over 10 yrs
  - Estimated cost to Centers for Medicare and Medicaid Services for delay of generic drug availability

Life sciences exemption – Congressional Budget Office

- In response, BIO's General Counsel Tom DiLenge noted that "IPR is not designed to speed generic entry"
- Also noted that $130M per year, while large in absolute terms, is a relatively small amount of money and won't much affect generic entry
- DiLenge further observed that the pharmaceutical industry is unified in its opposition to allowing drug patents to be challenged using IPR

Assessment

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Assessment

- Post-grant limitations
- Life sciences exemption

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Post-Grant Resources

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Resources

- Fish web sites:
  - Post-Grant for Practitioners: http://fishpostgrant.com/webinars/
  - General: http://fishpostgrant.com/
  - IPR: http://fishpostgrant.com/inter-partes-review/
  - PGR: http://fishpostgrant.com/post-grant-review/
  - Rules governing post-grant: http://fishpostgrant.com/
  - Post-Grant App: http://fishpostgrant.com/app/

- USPTO sites:
  - AIA Main: http://www.uspto.gov/aia_implementation/index.jsp
  - Inter Partes: http://www.uspto.gov/aia_implementation/bpai.jsp

Thank You!

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