November 12, 2015

Post-Grant for Practitioners

Bio-Pharma Developments: Bass, Biologics, and Small Molecules

Dorothy Whelan
Principal, Post-Grant Practice
Co-Chair

Tasha Francis
Associate

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Agenda

I. Overview of Webinar Series
II. BioPharma Statistics
III. IPRs filed by NPEs
IV. IPRs & Biologics
V. Post-Grant Resources

Overview of Webinar Series

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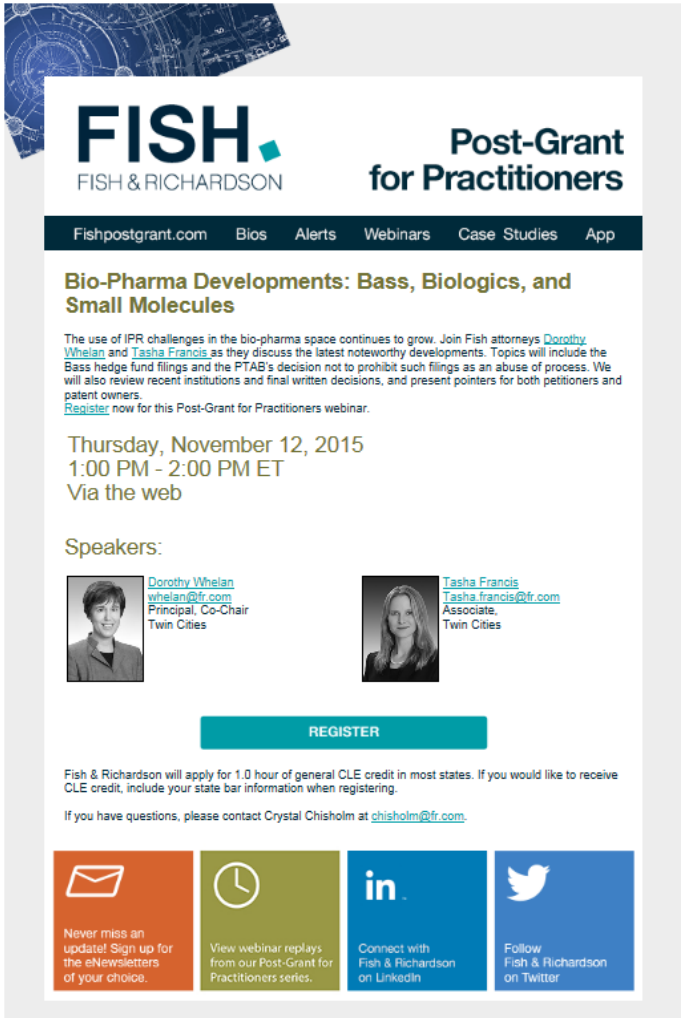
Overview

- 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

Fishpostgrant.com Bios Alerts Webinars Case Studies App

Bio-Pharma Developments: Bass, Biologics, and Small Molecules

The use of IPR challenges in the bio-pharma space continues to grow. Join Fish attorneys Dorothy Whelan and Tasha Francis as they discuss the latest noteworthy developments. Topics will include the Bass hedge fund filings and the PTAB's decision not to prohibit such filings as an abuse of process. We will also review recent institutions and final written decisions, and present pointers for both petitioners and patent owners.
Register now for this Post-Grant for Practitioners webinar.

Thursday, November 12, 2015
1:00 PM - 2:00 PM ET
Via the web

Speakers:

Dorothy Whelan
whelan@fr.com
Principal, Co-Chair
Twin Cities

Tasha Francis
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Associate,
Twin Cities

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.

Never miss an update! Sign up for the eNewsletters of your choice.

View webinar replays from our Post-Grant for Practitioners series.

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BioPharma Statistics

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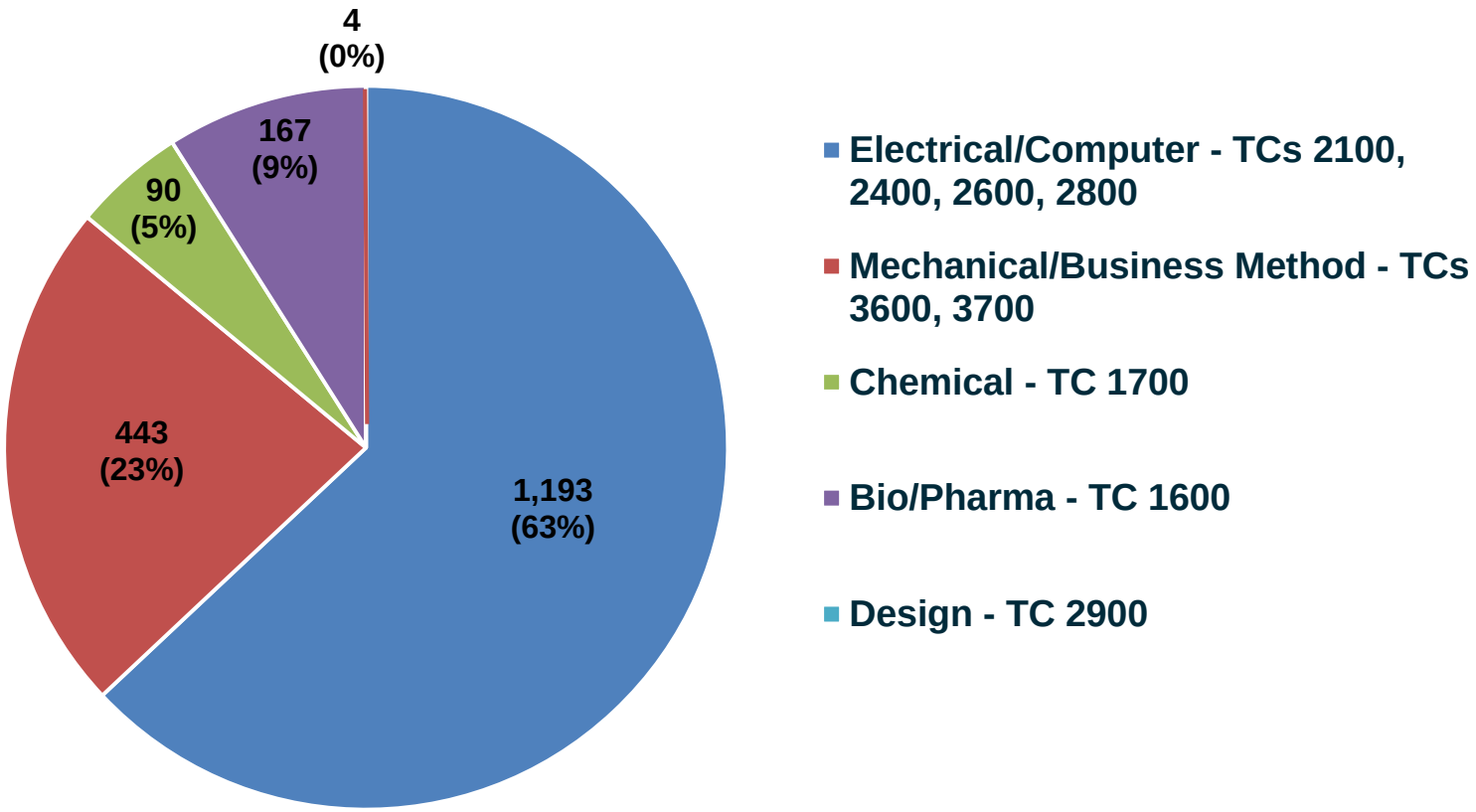
IPR Statistics (for FY2015 through 9/30/2015)

AIA Petition Technology Breakdown



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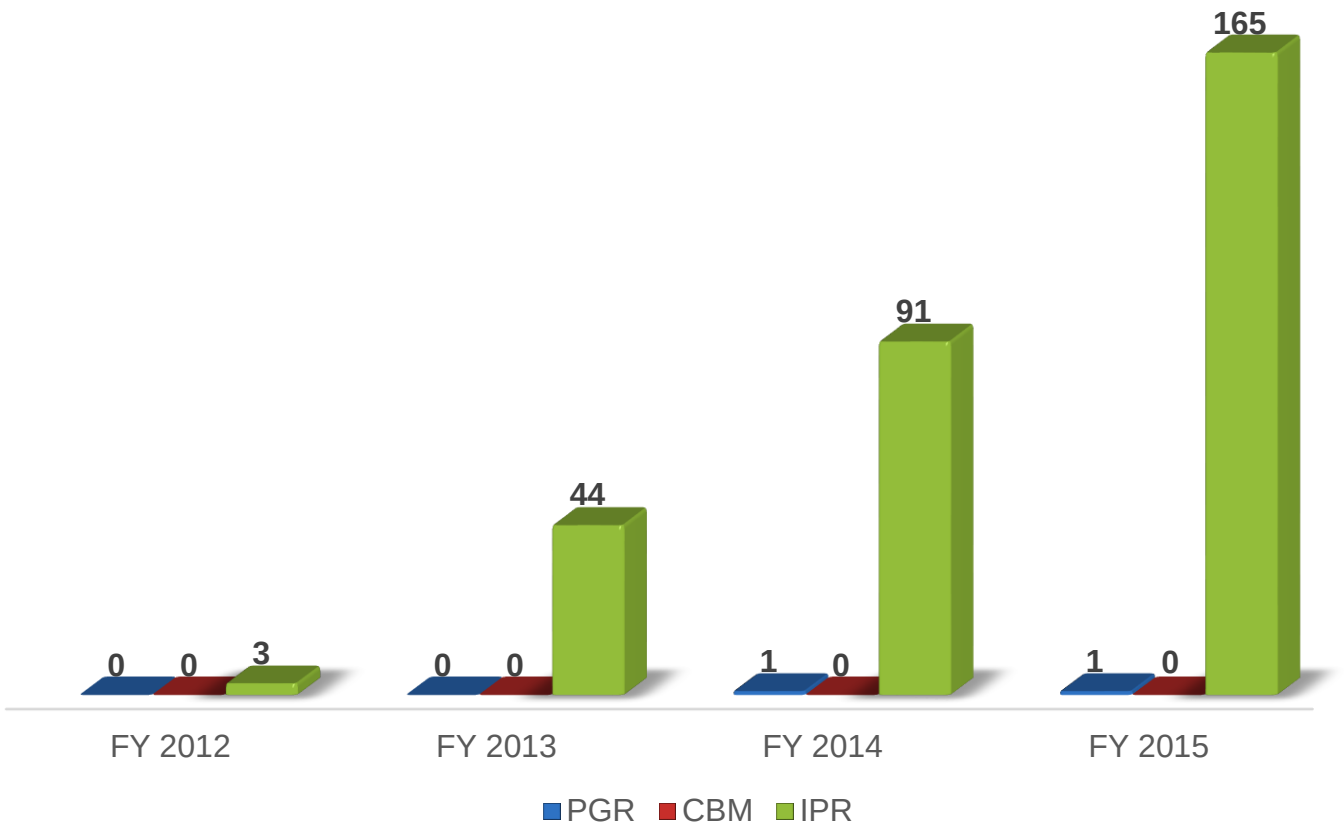
BioPharma IPR Statistics (as of 9/30/2015)

AIA Petitions Filed by Fiscal Year by Type from TC1600



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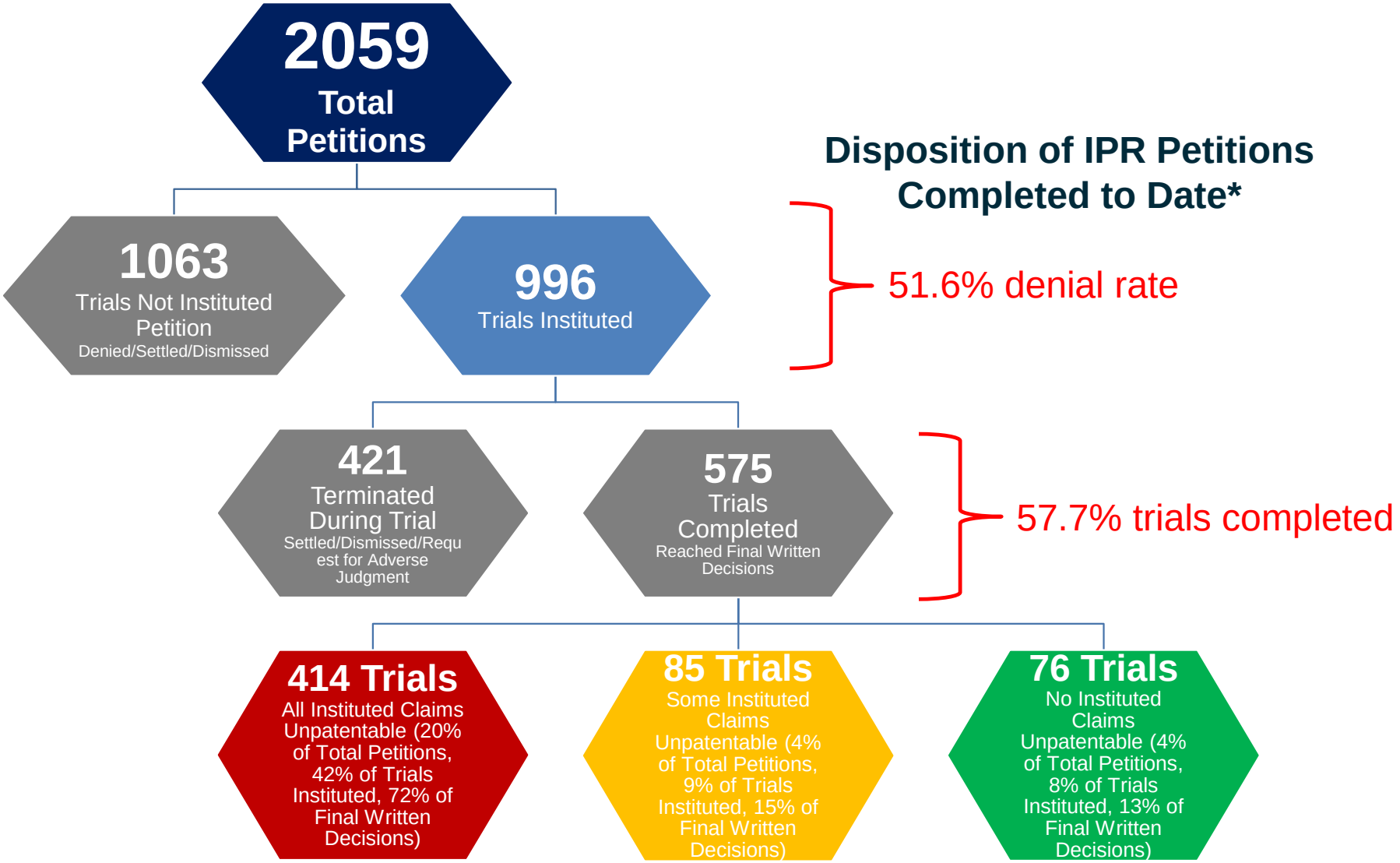
Janet Gongola, "Protecting Biopharmaceutical Innovation-Litigation and Patent Office Procedures" (2015).

IPR Statistics (as of 9/30/2015)



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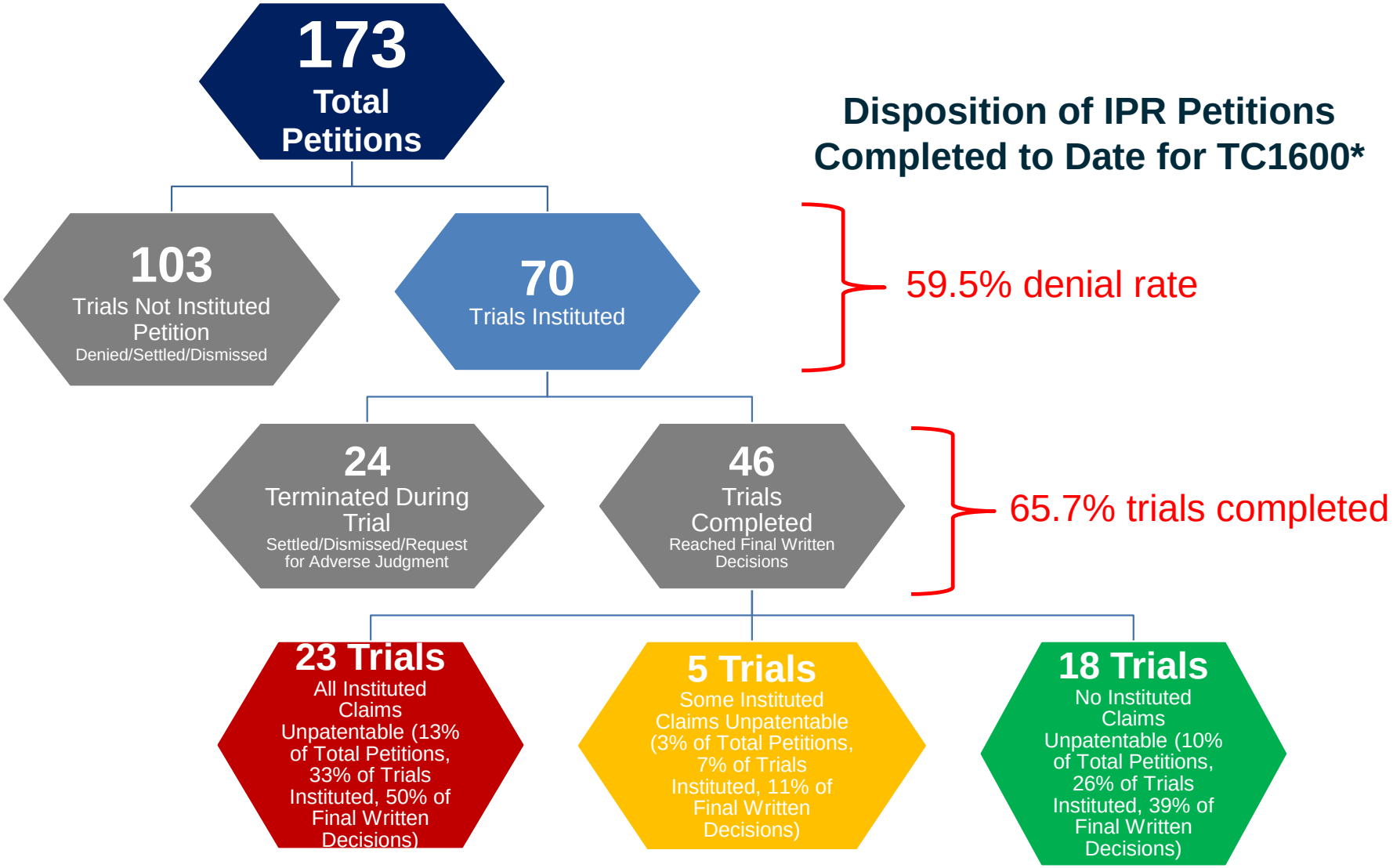
Janet Gongola, "Protecting Biopharmaceutical Innovation- Litigation and Patent Office Procedures" (2015).

BioPharma IPR Statistics (as of 9/30/2015)

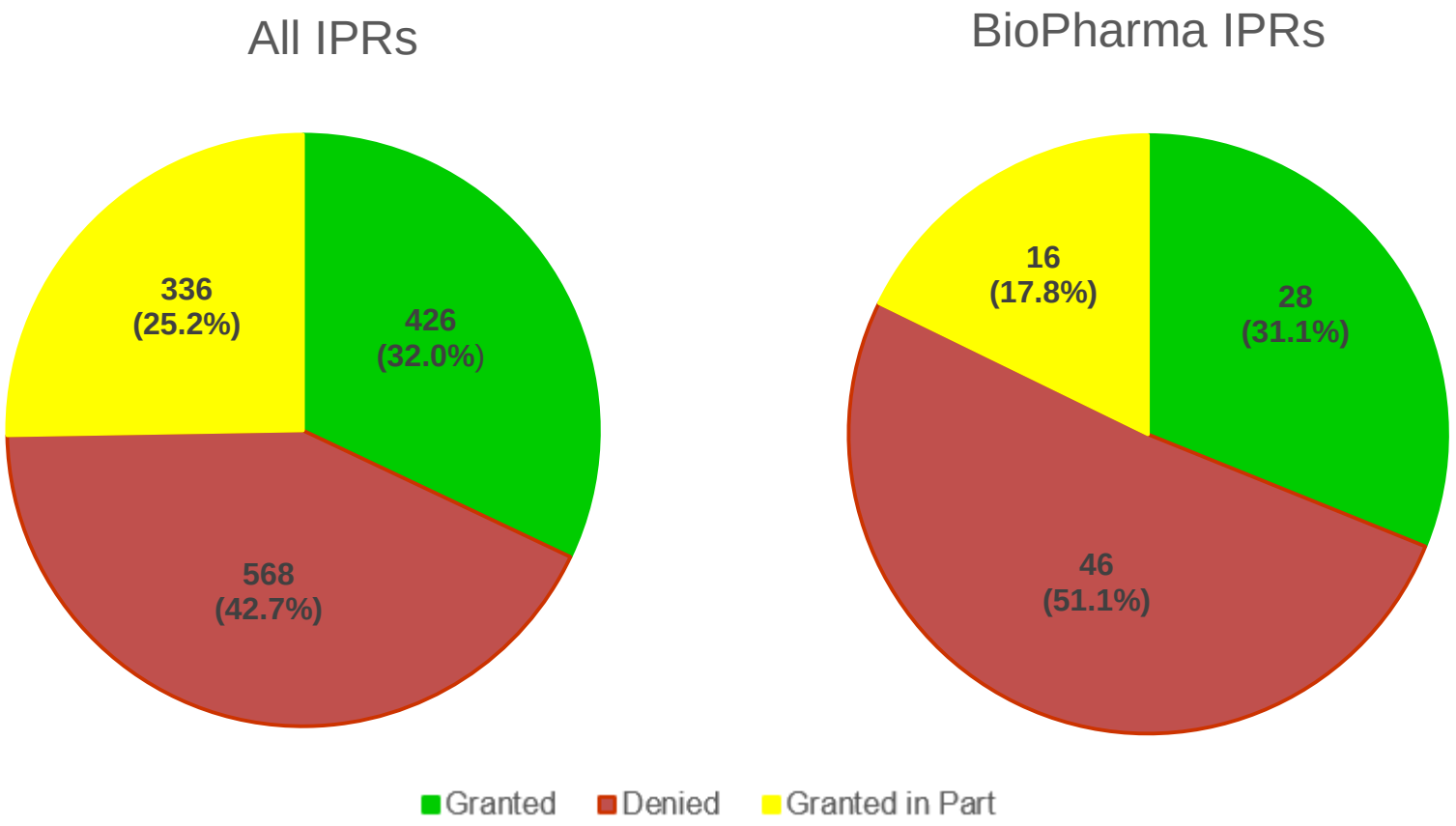


FISH.

Janet Gongola, "Protecting Biopharmaceutical Innovation- Litigation and Patent Office Procedures" (2015).

BioPharma Statistics (for FY2015 through 10/31/2015)

- The trend continues in 2015: BioPharma IPR petitions are denied institution more often



Types of BioPharma Patents Challenged

Core patents vs. follow-on patents

- In an analysis of 200 IPRs of biopharma patents
- ~ 17% targeted core patents
  - Drug composition claims
    - ~ 13% drugs; ~4% biologics
- ~ 84% targeted follow-on patents
  - Claims to drug product uses, formulation or manufacturing processes
    - ~ 41% targeted treatment methods
    - ~ 34% targeted product formulations
    - ~ 8% targeted manufacturing or distribution processes

34 Biotechnology Law Report 185(5) Nov. 5, 2015

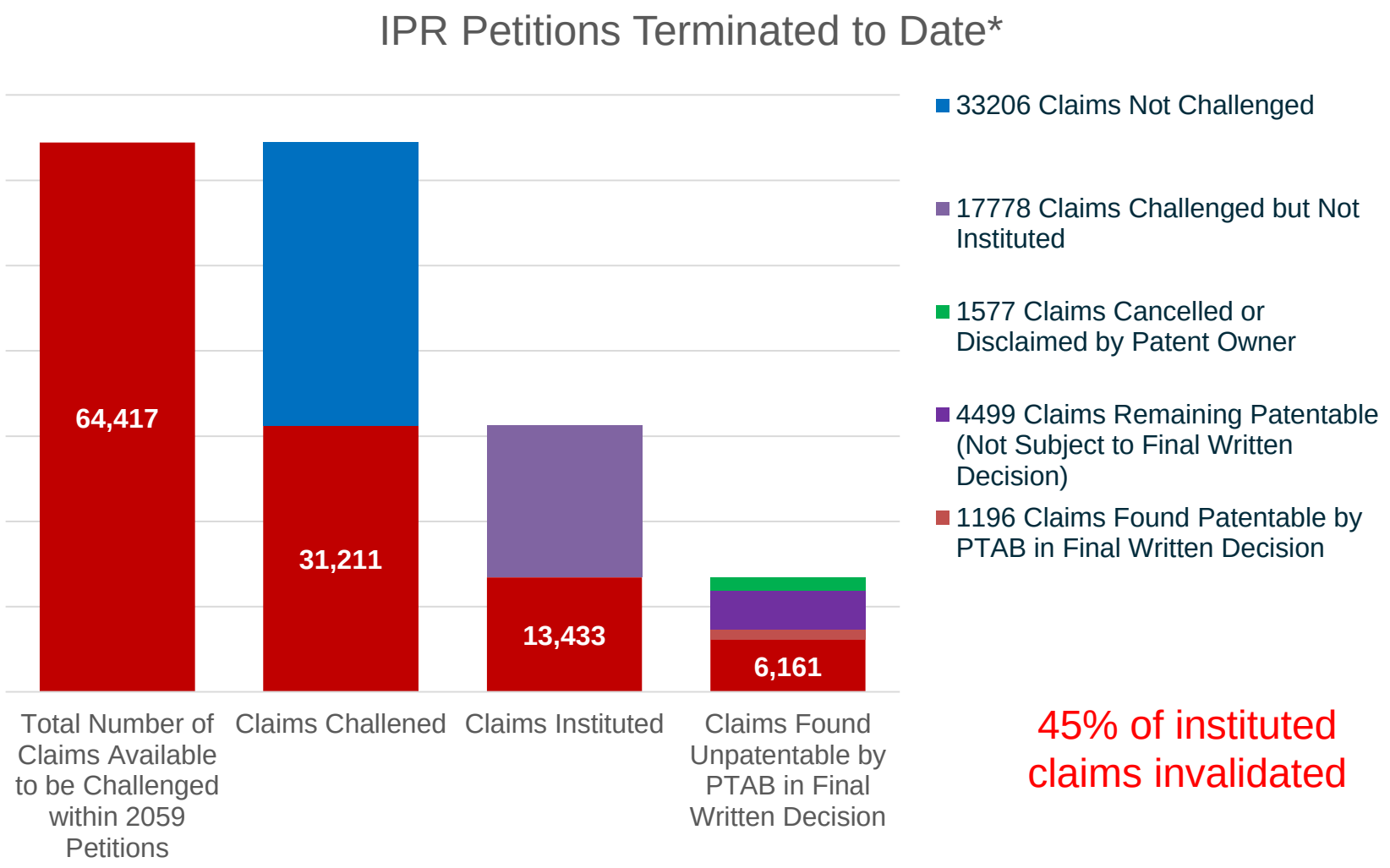
Types of BioPharma Patents Challenged

Core patents vs. follow-on patents

- Challenged core patents
  - 30% institution rate
  - 2% of these IPR settled
  - Final decision has been reached in only one of the analyzed IPRs challenging a core patent
    - Majority of claims were held unpatentable
- Challenged follow-on patents
  - 48% institution rate
  - 18% of these challenges settled
  - Final decision reached in 23 analyzed follow-on patent IPR challenges
    - In 65%, all or most claims were held unpatentable

34 Biotechnology Law Report 185(5) Nov. 5, 2015

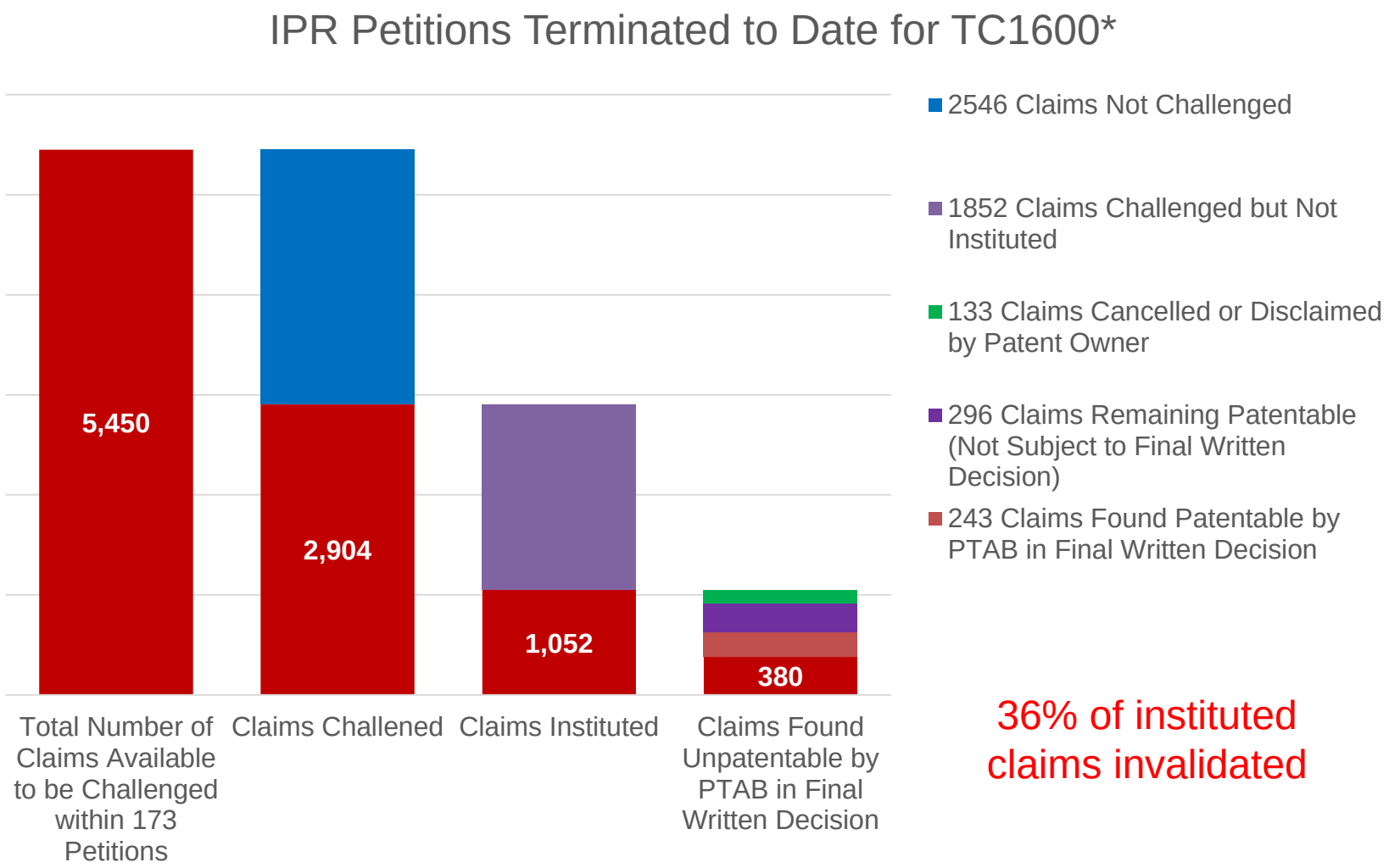
Statistics Post Institution (as of 9/30/2015)



45% of instituted claims invalidated

Janet Gongola, "Protecting Biopharmaceutical Innovation-Litigation and Patent Office Procedures" (2015).

BioPharma Stats Post Institution (as of 9/30/2015)



36% of instituted claims invalidated

Janet Gongola, "Protecting Biopharmaceutical Innovation-Litigation and Patent Office Procedures" (2015).

Who is filing IPRs in the Pharma space?

Generics

- Accord Healthcare
- Amneal
- Apotex
- Aurobindo
- Breckenridge
- Impax
- Mylan
- Par
- Perrigo
- Ranbaxy
- Roxanne
- Sandoz
- Sun
- Torrent

Non-Generics

- BioDelivery Sciences
- Eli Lilly
- Endo
- Galderma
- MonoSol Rx
- Phigenix
- Purdue
- Shire
- St Jude

NPEs

- Kyle Bass
- Ferrum Ferro Capital

Post-Grant: Representative list - who has been targeted?

Allergan
Alza
Alcon Pharma
Brigham and Women's Hospital
BTG International
Choongwae Pharma. Corp.
Cubist

Depomed
Eli Lilly
Endo
Genentech
Gilead
Grifols SA
Helsinn Healthcare SA
Immunogen
Jazz Pharma.

LifeScan
Kyoto University
Mayo
Merck
MonoSol RX, LLC
Myriad Genetics
Novartis
Reckitt Benckiser
Roche Palo Alto

Senju Pharma. Co., Ltd
Supernus
UCLA Med. Ctr.
Univ. of Michigan
Univ. of Utah
Vertex
Viiv Healthcare
Wyeth (Pfizer)

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IPRs filed by NPEs

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Hedge Fund Petitioners

- Kyle Bass and various related entities, including the Coalition for Affordable Drugs, have filed a total of 33 IPR petitions to date.
- The Coalition for Affordable Drugs is a series of companies, each formed for a particular IPR petition
- Targets include Biogen, Celgene, Pozen, Shire, Acorda, and NPS Pharmaceuticals
- Latest filed September 28, 2015 against Biogen

Post-Grant for Practitioners

Abuse of Process?

- Celgene and Pharmacyclics filed motions for sanctions against Bass seeking dismissal of the petitions as an abuse of process
- Celgene alleged that Spangenberg (co-Petitioner) threatened to file IPRs against Celgene to extract a settlement.
- When Celgene didn't respond, the Initiative for Responsibility in Drug Pricing ("IRDP") sent a nearly identical petition to Celgene, seeking a cash settlement.
- When Celgene still didn't respond, Spangenberg and IRDP joined forces with Bass to form shell companies (Coalition for Affordable Drugs) for the purpose of challenging patents held by pharma companies while betting against their shares.

PTAB: Bass May Be Bad, But He's Legal

Trials@uspto.gov
571.272.7822

Paper No. 19
Filed: September 25, 2015

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

COALITION FOR AFFORDABLE DRUGS VI, LLC,
Petitioner,
v.
CELGENE CORPORATION,
Patent Owner.

Case IPR2015-01092 (Patent 6,045,501)
Case IPR2015-01096 (Patent 6,315,720)
Case IPR2015-01102 (Patent 6,315,720)
Case IPR2015-01103 (Patent 6,315,720)
Case IPR2015-01169 (Patent 5,635,517)[1]

Before TONI R. SCHEINER, MICHAEL P. TIERNEY, MICHAEL W. KIM, JACQUELINE WRIGHT BONILLA, GRACE KARAFFA OBERMANN, and TINA E. HULSE, *Administrative Patent Judges*.

TIERNEY, *Administrative Patent Judge*.

DECISION
Denying Sanctions Motion
37 C.F.R. § 42.12

[1] This Order addresses issues common to all identified cases. We exercise our discretion to issue one Order to be filed in each case. The parties are not authorized to use this style heading.

DECISION
Denying Sanctions Motion
37 C.F.R. § 42.12

"We take no position on the merits of short-selling as an investment strategy other than it is legal, and regulated."

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Post-Grant for Practitioners

Hedge Fund Petitioners

- **The PTAB has denied institution in 6 Bass IPRs**
  - Jazz Pharmaceuticals (Xyrem®)
    - IPR2015-01018
  - Acorda Therapeutics (Ampyra®)
    - IPR2015-00720
    - IPR2015-00817
  - Pharmacyclics (Imbruvica®)
    - IPR2015-01076
  - Biogen (Tecfidera®)
    - IPR2015-01086
    - IPR2015-01136

Reasons Bass IPRs were denied

- References relied upon were found not to be publicly available and therefore not prior art
  - Webpages said to disclose clinical trial data but without adequate information about when and how much information was publicly available (IPR2015-01076)
  - Posters presented at conferences were not proven to be sufficiently publicly available (IPR2015-00720, -00817)
  - Transcript of an FDA Advisory Committee hearing was not proven to be publicly available (IPR2015-01018)

Hedge Fund Petitioners

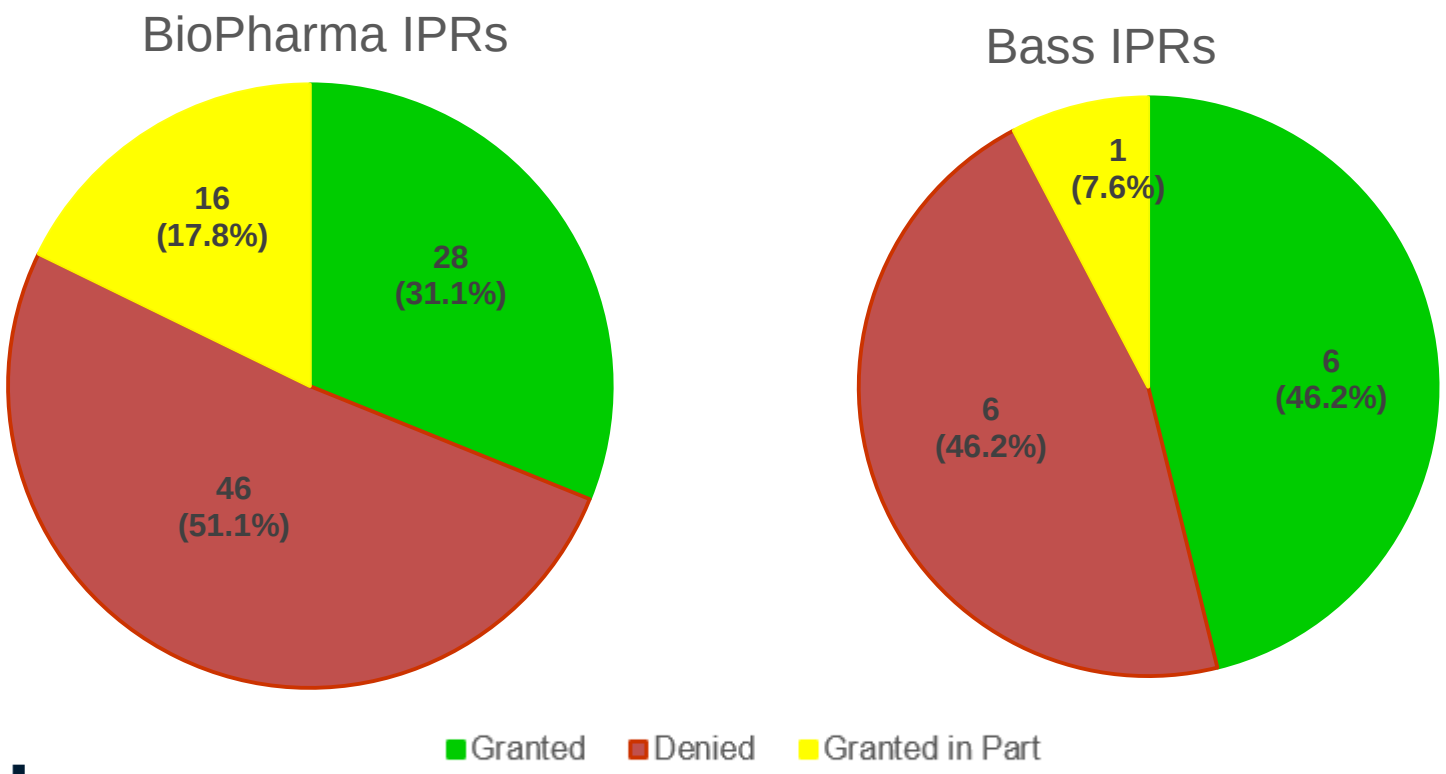
- **PTAB has instituted IPR review in 7 Bass IPRs**
  - Shire Inc. (Lialda®)
    - IPR2015-00988
      - Oral hearing scheduled June 24, 2016
  - NPS Pharmaceuticals (Gattex®)
    - IPR2015-00990
    - IPR2015-01093
      - Oral hearing scheduled June 23, 2016
  - Celgene Corp. (Pomalyst® and Revlimid®)
    - IPR2015-01092
    - IPR2015-01096
    - IPR2015-01102
    - IPR2015-01103

Reasons Why Bass IPRs Were Instituted

- Patent Owner's arguments regarding commercial success and long-felt need were not successful
  - PO failed to provide evidence [as opposed to "argument and conclusory contentions"] to permit a determination as to whether the long-felt need was met by the discovery of GLP-2 analogs…IPR2015-00990, 01093
- Patent Owner's arguments that petitions should be denied based on failure to identify RPIs were unsuccessful

Hedge Fund Petitioners

- **Bass has high rate of institution with review being instituted on most claims**



Successful Strategy?

Hedge fund strategy may have been successful at first:

Accorda Therapeutics

Shire Pharmaceuticals

But recent studies suggest the approach may not be sustainable:

Upon filing of IPR2015-00136, Biogen's stock actually gained 3.29% the day after, 6.55% within one week, and 5.19% over the following month.

http://patentvue.com/2015/10/20/challenge-the-patent-and-short-the-stock-does-it-really-work/

Other NPEs filing IPR Petitions

Other NPEs filing IPR petitions

- Ferrum Ferro Capital
  - IPR2015-00858 versus Allergan's '149 patent covering Combigan
  - Institution denied
- New Bay Capital
  - 4 IPR petitions filed
  - All four settled
- Mangrove Partners Masters Fund
  - 2 IPR petitions filed and instituted
- Erich Spangenberg
  - Founder of IPNav
  - Has sued over 1,600 companies for patent infringement
  - Real Party in Interest in Bass' filings

Eric Spangenberg

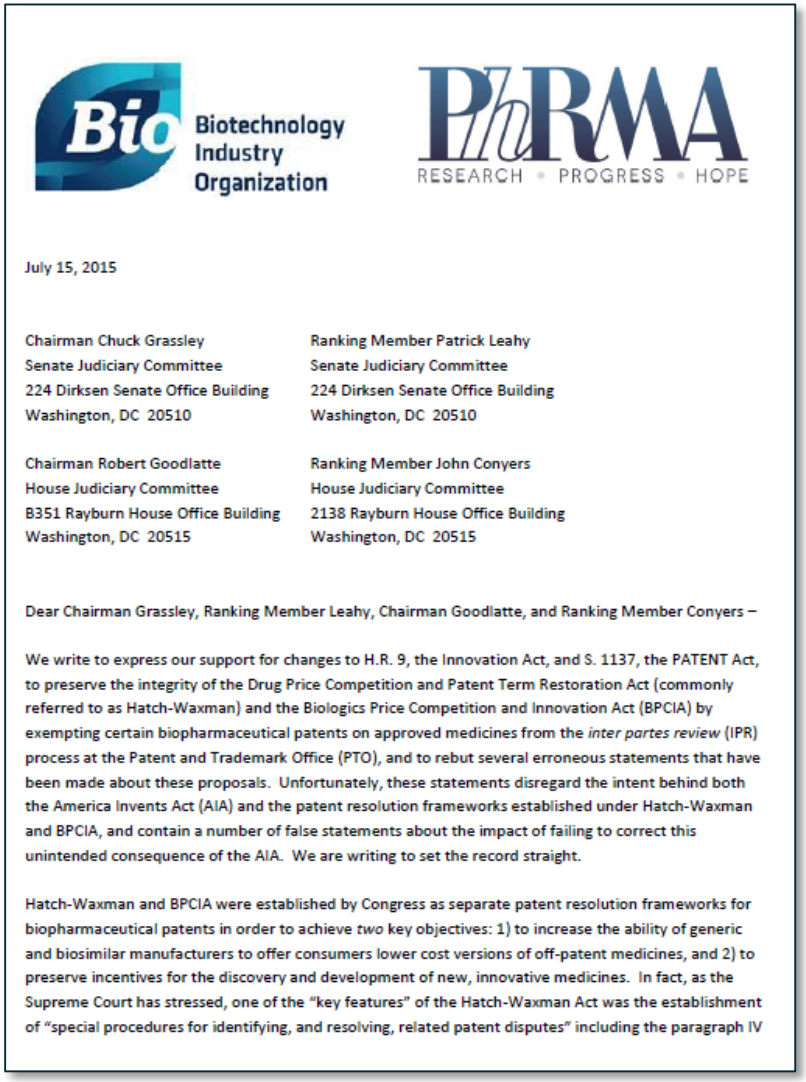
- Recently used his blog (spangenblog) to solicit volunteers to fund and file IPR petitions
- Spangenberg stated his background makes him “the wrong person to be the face of this effort,” and hopes others, for example, a law school group, charitable organization or a consumer protection group, will take up the cause.
- On September 29, 2015, Spangenberg posted a 63-page draft IPR petition of the Depomed patent covering Nucynta®.

Factors Putting Patents in Spangenberg's Crosshairs

- Spangenberg stated ever-greening patents will typically have the following attributes:
  - more than 100 references on the cover page
  - a four (or greater) year gap between the expiration date of the patent and the previous patents listed with the drug in the FDA's "Orange Book" of approved drugs
  - a convoluted prosecution history — "typically the patent was prosecuted by some mega law firm that simply wore down the patent examiner"
  - multiple uses of the phrase "surprising result" or "unexpected result" in the patent specification

Should IPRs Not Apply to BioPharma?

In July 2015, a group of 80 House members signed a letter urging the addition of language to H.R.9 to exempt certain biopharmaceutical patents from IPR review



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

Legislative Reform

Hedge Fund Petitioners

Proposed legislation:

(1) Preclude hedge funds from filing petitions;

Innovation Act of 2015 includes a provision requiring parties seeking IPR of a granted patent to certify that they do not have a financial interest in seeing the stock of the patent holder decline

(2) Standing requirement

STRONG Patent Act of 2015 proposes to limit standing to file and IPR to those “sued for infringement of the patent” or “charged with infringement under the patent,” and their privies and real parties in interest- much like the current standing for CBM petitions

IPRs & Biologics

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Post-Grant for Practitioners

Biologics IPRs

- A number of biosimilar makers have turned to IPR to challenge innovator patents prior to submitting their biosimilar applications to the FDA
- Examples include
  - Boehringer Ingelheim
    - IPR2105-00415, -417, -418 challenging patents covering Rituxan®
  - Hospira
    - IPR2013-00365 challenging patents covering dosing regimens for administering erythropoietin (EPO)IPR2013-00365 challenging Eprex (epoetin alfa), a biologic used to treat anemia
  - Amgen
    - IPR2015-01514, -1517 challenging patents covering Humira®

Post-Grant for Practitioners

Biologics IPRs

- Biosimilar manufacturers view IPRs as advantageous
  - Provide for a sort of freedom to operate analysis
  - Claims are construed with the broadest reasonable interpretation
    - Generally broader claim construction than district court
  - No presumption of patent validity
  - Invalidity need be proved only by “preponderance of the evidence”
    - As opposed to “clear and convincing evidence”
  - Decisions rendered faster
  - Allows for patent certainty when litigation under Biologics Price Competition and Innovation Act of 2009 (BPCIA) is premature

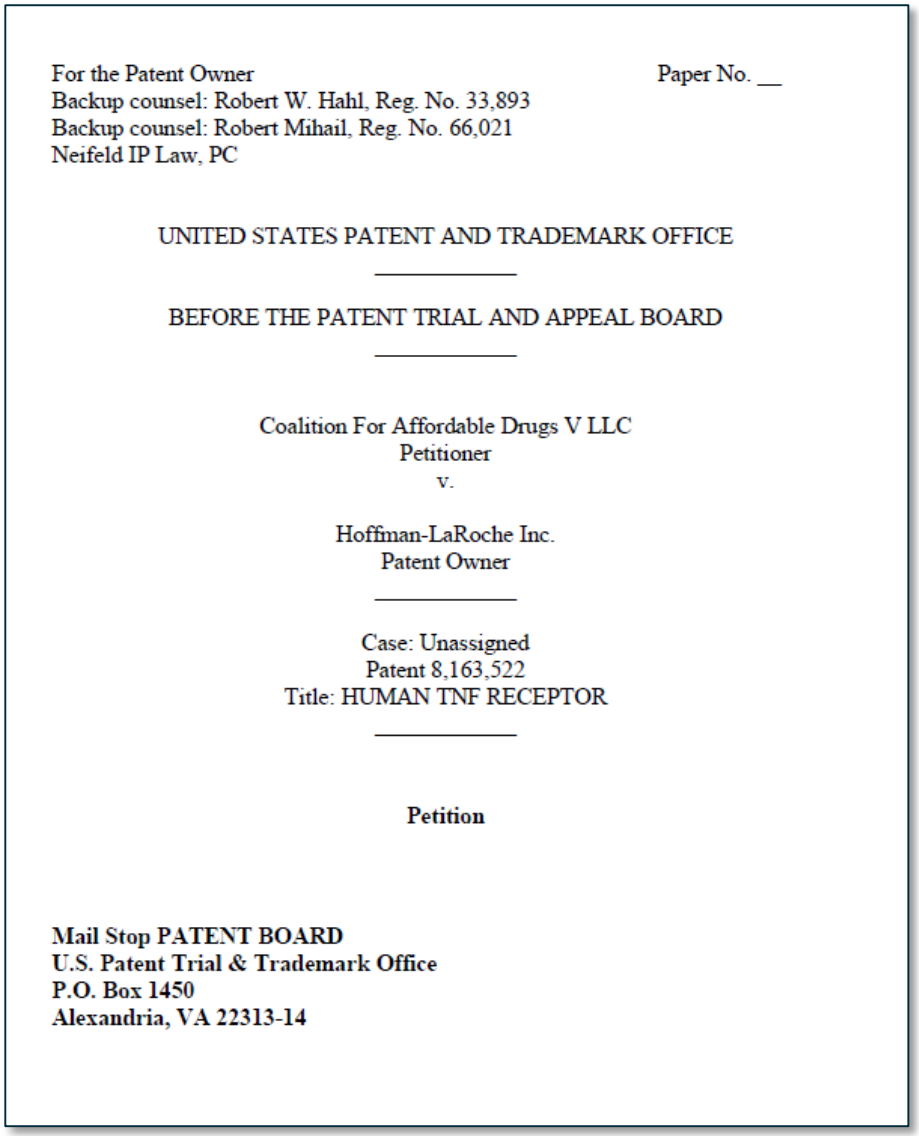
Post-Grant for Practitioners

Boehringer Ingelheim

- Developing a biosimilar of Biogen and Genetech's antibody product Rituxan®
- Early adopter of IPR in lieu of BPCIA litigation
- Boehringer filed IPR petitions in December 2014 challenging three patents covering Rituxan®
  - Patents do not expire until 2020 or later
- Strategy has mixed results
  - IPR2015-00417 instituted on all claims of 7,976,838 patent
  - IPR2015-00415 not instituted on half of challenged claims of 7,820,161 patent
  - IPR2015-00418 filed against 8,329,172 patent not instituted
- Board's decision not to institute IPR for all claims in '161 and '172 patents leaves those patents for BPCIA litigation
  - Board's decision likely strengthens these patent claims

NPEs & Biologics

While Bass has targeted mainly small molecule patents, IPR2015-01792 targets Hoffman-LaRoche's U.S. Patent 8,163,522 covering the biologic Enbrel®



For the Patent Owner
Backup counsel: Robert W. Hahl, Reg. No. 33,893
Backup counsel: Robert Mihail, Reg. No. 66,021
Neifeld IP Law, PC

Paper No. __

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Coalition For Affordable Drugs V LLC
Petitioner
v.

Hoffman-LaRoche Inc.
Patent Owner

Case: Unassigned
Patent 8,163,522
Title: HUMAN TNF RECEPTOR

Petition

Mail Stop PATENT BOARD
U.S. Patent Trial & Trademark Office
P.O. Box 1450
Alexandria, VA 22313-14

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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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@FishPostGrant

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