

# Post-Grant for Practitioners



FR

## Part IX: Inter Partes Review and the Life Sciences



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Post-Grant Practice*

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## Agenda

- I. Overview of Webinar Series
- II. Statistics
- III. Pharmaceutical Applications
- IV. Other Life Sciences Applications
- V. **Patent Owner's Perspective**

## I. Overview

Where? ... see invitation

How often? ... monthly

When? ... 2<sup>nd</sup> Wednesday

Topics? ...

Important decisions

Developments

Practice tips

FR FISH & RICHARDSON

Post-Grant Practice



### **Post-Grant for Practitioners:**

A monthly series of webinars focusing on developments in post-grant proceedings and related practice tips

#### **Part I: Inter Partes Review and Covered Business Method Patents - the First Five Months.**

Wednesday, February 13, 2013  
1:00 p.m. ET

Fish & Richardson's post-grant practice chairs are back with a new monthly series of webinars devoted to topics of interest in the emerging area of post-grant proceedings. Join them as they share their experiences, insights, and practice tips.

This first webinar will discuss the first five months of inter partes review and covered business method patents.

#### **Speakers:**

[Dorothy Whelan](#), Principal and Post-Grant Practice Co-Chair, Twin Cities  
[Karl Renner](#), Principal and Post-Grant Practice Co-Chair, Washington, DC

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

RSVP

If you have questions, please contact Tracey Spadavecchia at [spadavecchia@fr.com](mailto:spadavecchia@fr.com).

## I. Overview (con't)

- Housekeeping
  - CLE
  - Questions
  - Materials
    - 2012 & 2013 Webinar series: <http://fishpostgrant.com/webinars/>

## II. Statistics (IPR)

- **IPR's Filed?**
  - 533 filed through October 4th
  - 75 filed in September
- **Application of Threshold: Reasonable Likelihood of Success**
  - IPR has been instituted in almost all petitions evaluated.
  - In many cases where IPR was ordered, it was on only a subset of petitioned claims and/or a subset of proposed grounds.
  - There has been an uptick in the number of IPR petitions denied in full.

## II. Statistics (CBM)

- **CBM's Filed?**
  - 53 filed through October 4th
  - 5 filed in September
- **Application of Threshold: Reasonable Likelihood of Success**
  - CBM instituted in vast majority of CBM Petitions that were evaluated
  - In a number of cases, CBM was ordered on only a subset of petitioned grounds and/or claims

## II. Statistics

Who is filing (IPR, CBM, DER)?

- Electrical/Computer: 68.5%
- Mechanical: 13.5%
- Chemical: 9.5%
- Bio/Pharma: 7.6%
- Design: 0.9%

Source: [http://www.uspto.gov/ip/boards/bpai/stats/aia\\_trial\\_statistics.jsp](http://www.uspto.gov/ip/boards/bpai/stats/aia_trial_statistics.jsp)

## II. Statistics (Stays)

### Granted (51):

C.D. CA  
 Semiconductor Energy Lab Co., Ltd. v. Chimei Innolux Corp. et al.  
 Star Envirotech Inc. v. Redline Detection LLC  
 AutoAlert, Inc. v. Dominion Dealer Solutions, LLC  
 Pi-NET International, Inc. v. The Hertz Corp.

N.D. CA  
 Grobler v. Apple Inc. (granted in part)  
 Grobler v. Sony Computer Entertainment America LLC  
 PI-Net International Inc. v Focus Business Bank  
 Droplets, Inc. v. Amazon, Inc. et al.  
 Software Rights Archive LLC v. Facebook, Inc.  
 Samuels v. TriVascular Corporation

COFC  
 Cheetah Omni, LLC v. USA

D. CO  
 Fiber, LLC v. Ciena Corporation, et al

D. DE  
 Softview LLC v Apple Inc. (Stark)  
 Trustees of Columbia University in the City of New York v. Illumina, Inc.  
 Neste Oil Oyj v. Dynamic Fuels LLC

M.D. FL  
 Capriola Corp. v. Larose Industries, LLC

N.D. GA  
 Coprecitec, S.L. et al v. The Brinkmann Corp.,

C.D. IL  
 Bd. Of Trustees of the Univ. of Illinois v. Micron Tech., Inc.

N.D. IL  
 Clearlamp LLC v. LKQ Corp.  
 Bergstrom, Inc. v. Idle Free Sys., Inc.  
 ComplementSoft, LLC v. SAS Institute, Inc.

D. KS  
 Select Brands, Inc. v. Sensio, Inc.

W.D. KY  
 SSW Holding Company Inc. v Schott Gemtron Corp.

S.D. NY  
 Aqua Products, Inc. v. Zodiac Pool Systems

N.D. OH  
 Progressive Casualty Ins. Co. v. Safeco Ins. Co. of Ill.  
 Nutech Ventures v. Norman Noble, Inc.  
 Bennett Regulator Guards, Inc v. Atlanta Gas Light Company, et al



## Granted (continued) (51):

S.D. OH

Escort Inc. v. K-40 Electronics, LLC

D. MN

Cutsforth, Inc. v. LEMM Liquidating Co.,

E.D. PA

Pride Mobility Products Corp. V Permobil

Arkema, Inc. et al. v. Honewell Intl., Inc.

Bernina International AG v. Handi Quilter, Inc.

W.D. PA

Centria v. ATAS International, Inc

E.D. TX

Network-1 Sec. Solutions, Inc. v. Alcatel-Lucent USA Inc. et al.

Achatas Reference Pub., Inc. v. Symantec Corp.

Merck v. Macoven Pharmaceuticals et al.

Uniloc USA, Inc. et al. v. Distinctive Developments Ltd.

N.D. TX

Taylor Publishing Company v CTP Innovations LLC

W.D. TX

E-Watch, Inc. v. ACTi Corporation

S.D. TX

E-Watch, Inc. v. FLIR Systems, Inc.

E-Watch, Inc. v. Lorex Technology, Inc. et al.

M.D. TN

CTP Innovations LLC v. Waldsworth Publishing

CTP Innovations LLC v. Textile Printing Company

CTP Innovations LLC v. MPI Label Systems

CTP Innovations LLC v. American Printing Company

CTP Innovations LLC v. Jet Printing, LLC

CTP Innovations LLC v. Magna IV Color Imaging

CTP Innovations LLC v Dickinson

CTP Innovations LLC v Ambrose

CTP Innovations LLC v Edwards Brothers

E.D. WI

Prolitec, Inc. v. ScentAir Technologies, Inc.

## Denied (19):

C.D. CA

Universal Electronics v. Universal Remote Control Inc.

N.D. CA

Ariosa Diagnostics, Inc. v. Sequenom, Inc.

S.D. CA

Whalen Furniture Mfg., Inc. v. Z-Line Designs, Inc.  
Warsaw Orthopedic Inc. v. NuVasive Inc.

D. DEL

General Electric Co. v. Vibrant Media, Inc.  
Davol, Inc. v. Atrium Medical Corp.  
ViiV HealthCare Co. v. Mylan

M.D. FL

Automatic Manufacturing Systems, Inc. v. Primera  
Technology, Inc.

N.D. IL

SRAM, LLC v. HB Suspension Prods., LLC,

D. MA

Trustees of Boston University v. Everlight Electronics Co.,  
Ltd., et. al.

E.D. MI

Everlight Electronics Inc. v. Nichia Corp.

N.D. MN

Dane Technologies Inc. v Gatekeeper System Inc.

S.D. OH

The Procter &amp; Gamble Co. v. Team Technologies

N.D. NJ

Derma Sciences, Inc. et al v. Manukamed Ltd. et al.

N.D. NY

John Mezzalingua Associates, Inc. v. Corning Gilbert, Inc.

W.D. TN

One StockDuq Holdings, LLC v. Becton Dickinson and Co.

W.D. TX

National Oilwell Varco, LP v. Pason Systems USA Corp.  
National Oilwell Varco, LP v. Omron Oilfield & Marine, Inc.

W.E. TX

E-Watch , Inc. v. Mobotix Corp. (denied in part)

## II. Statistics (Stays)

Factors considered in denying requests for stays:

- Premature (IPR not ordered);
- Advanced stage of district court case;
- Undue prejudice to patent owner
- Stated desire of courts to resolve all issues

### III. Pharmaceutical Applications

IPR may offer some advantages over district court for challengers:

- Lower burden of proof (preponderance vs. clear and convincing);
- Generally faster and less expensive
- All direct testimony by declaration; no live testimony
- Opportunity to stay district court litigation
- PTAB generally more receptive to § 103 challenges

## III. Pharmaceutical Applications

IPR may be a useful tool in one or more of the following scenarios:

- Subsequent generic ANDA filers
- Obviousness challenges
- Composition/Formulation claims
- Prodrugs
- Platform technologies
- Freedom to operate (FTO) scenarios

## III. Pharmaceutical Applications

### BACKGROUND – Hatch Waxman

- Manufacturer of generic version of branded drug files an **Abbreviated New Drug Application (“ANDA”)** when it wishes to enter the market.
- **ANDA includes a statement (“Paragraph IV certification”, “P4”)** that **patent(s) covering the drug and listed in the FDA’s Orange Book are invalid, unenforceable, and/or not infringed.**
- If the (first) ANDA filer successfully challenges the patent in district court, it receives a 180 day exclusivity period in which to market the drug.
- Subsequent generic filers are not eligible for the exclusivity period.

## III. Pharmaceutical Applications

### Representative Examples – Hatch Waxman

#### 1. Apotex Inc. v Alcon Pharmaceuticals Ltd., IPR2013-00012 and -00015

- Patents related to an ophthalmic composition.
- **Apotex was a “second” generic filer. Alcon sued Apotex in district court.**
- The first generic P4 filer, Teva, challenged the patent in district court and lost.
- The PTAB granted **Apotex’s** IPR petition that relied on the same art that Teva unsuccessfully raised in the district court.
- Petition granted on obviousness grounds.
- District court litigation against Apotex recently settled
  - IPRs still pending as of 10/08/2013

## III. Pharmaceutical Applications

### Representative Examples – Hatch Waxman

#### 2. Ranbaxy Laboratories Ltd. v. Vertex Pharmaceuticals Inc., 2013-00024

- Patent related to a prodrug (phosphate ester salt of a known protease inhibitor).
- Ranbaxy was a second generic ANDA filer. Vertex sued Ranbaxy in district court.
- **The PTAB granted Ranbaxy's IPR petition challenging the claims on § 103 grounds.**
- **PTAB adopted “lead compound” analysis (compound known, solubility problem associated with compound known, salts generally known to improve solubility).**



## III. Pharmaceutical Applications

### Representative Examples – Hatch Waxman

#### 3. Amneal v. Supernus, IPR2013-00368; -00371; -00372

- Three separate IPR petitions. Patents related to once-daily, sustained release formulations of doxycycline and methods of use.
- Amneal was a second generic filer. Supernus sued Amneal in district court.
- PTAB decision on petitions expected in December, 2013.

## III. Pharmaceutical Applications

### Representative Examples – non-Hatch Waxman

#### 4. Gnosis v. Merck and South Alabama Medical Science Foundation, IPR2013-00116; -00117; -00118; -00119

- Four separate IPR petitions. Patents related to folate and L-methyl folate compositions, and methods of use.
- Merck/South Alabama sued Gnosis in district court and the ITC. ITC action subsequently terminated.
- IPR granted all 4 petitions on §§ 102 and 103 grounds.
- One of the patents was also the subject of a pending EPRx proceeding, which was stayed in favor of the IPR proceeding.

## Pharmaceuticals – other examples

1. Accord Healthcare v. Eli Lilly; IPR2013-00356; (US Patent 7,772,209; IPR **not** instituted)
2. Hospira, Inc. v. Janssen Pharmaceuticals, Inc.; IPR2013-00365 (US Patent 6,747,002; pending)
3. Cyanotech Corporation v. The Board of Trustees of the University of Illinois; IPR2013-00401 and -00404; (US Patent 5,527,533; pending)

## IV. Other Life Sciences Applications

IPR may offer some advantages over district court for challengers:

- Lower burden of proof (preponderance vs. clear and convincing);
- Generally faster and less expensive
- All direct testimony by declaration; no live testimony
- Opportunity to stay district court litigation
- PTAB generally more receptive to § 103 challenges

## IV. Other Life Sciences Applications

### A. Biotech

#### 1. Sequenom v. The Board of Trustees of the Leland Stanford Junior University, IPR2013-00390

- U.S. Patent 8,195,415 is the subject of co-pending district court litigation (next slide)
- The '415 patent is also involved in Interference No. 105,922, declared on May 3, 2013

#### 2. Ariosa Diagnostics v. ISIS Innovations, Ltd, IPR-2013-00250

- U.S. Patent 6,258,540 is the subject of co-pending district court litigation (next slide)

# United States Dist Ct for the Northern District of California, CA Nos.: 11-6391 SI, 12-0865 SI, and 12-5501 SI

IPR #	Petitioner	Patent	Patent holder	Related judicial proceedings	Stay?
IPR2013-00390	<u>Sequenom</u> ("Seq")	8,195,415	<u>Stanford</u> ("Stan")	Veri et al. v Seq et al, 12-865 SI; Interference No. 105,922	No
IPR2013-00308	Ariosa Diagnostics ("Ariosa")	8,296,076	Stan	Veri et al. v. Ariosa et al., 12-5501 SI	No
IPR2012-00022	Ariosa	6,258,540	<u>ISIS</u> Innovations, Ltd ("ISIS")	Ariosa v. Seq; Natera; Veri, 11-6391 SI	No
IPR2013-00250	Ariosa	6,258,540	ISIS	Ariosa v. Seq; Natera; Veri, 11-6391 SI	No
IPR2013-00276	Ariosa	8,318,430 Claims 1-18	<u>Verinata</u> Health, Inc. ("Veri")	Veri et al. v. Ariosa et al., 12-5501 SI	No
IPR2013-00277	Ariosa	8,318,430 Claims 19-30	<u>Artemis</u> Health, Inc. ("Art")	Veri et al. v. Ariosa et al., 12-5501 SI	No

## Biotech – other examples

1. Illumina v. Trustees of Columbia University; IPR2013-00011 (US Patent 8,088,575; pending)
2. Intelligent **Bio-Systems, Inc.** v. Illumina; IPR2013-00128 (US Patent 7,057,026; IPR instituted)
3. Intelligent **Bio-Systems, Inc.** v. Illumina Cambridge Limited; IPRs2013-00266 (US Patent 8,158,346; pending) and -00324 (US Patent 7,057,026; pending)

## IV. Other Life Sciences Applications

### B. Medical Devices

#### 1. Atrium Medical Corporation v. Davol, Inc., , IPR2013-00184, -00185, -00186, -00187, -00188, -00189

- Three IPRs filed against US Patent 7,785,334 (different subsets of claims)
- Two IPRs filed against US Patent 7,806,905 (different sets of claims)
- Requested that all the IPR petitions be consolidated before a single panel
- But, no IPR filed against US Patent 7,824,420
- Motion for stay denied (Judge Sleet, Ddel)
  - Even though two of the three stay considerations (issue simplification and stage of litigation) weighed in favor of granting the motion, the Court denied the motion to stay, finding that the risk of undue prejudice to the plaintiff resulting from a stay outweighed the potential benefits inter partes review could have on the litigation in terms of simplifying the case



## Medical Devices – other examples

1. Heart Failure Technologies, LLC v. CardioKinetix, Inc., IPR2013-00183 (US Patent 7,582,051; IPR not instituted)
2. NuVasive v. Warsaw Orthopedic, Inc., IPR2013-00206 (US Patent 8,251,997; IPR instituted)
3. NuVasive v. Warsaw Orthopedic, Inc., IPR2013-00208 (US Patent 8,251,997; IPR instituted)
4. Covidien LP v. Ethicon Endo-Surgery, Inc., IPR2013-00209 (US Patent 8,317,070; pending)
5. Becton Dickinson v. One StockDuq Holdings, IPR2013-00235 (US Patent 5,704,914; IPR instituted)
6. Lombard Medical Technologies, PLC v. Medtronic, Inc., IPR2013-00269 (US Patent 6,306,141; pending)
7. TriVascular, Inc. v. Shaun Samuels, IPR2013-00493 (US Patent 6,007,575; pending)
8. Smith & Nephew, Inc. v. Bonutti Skeletal Innovations, IPRs2013-00603, -00604, and -00605 (US Patents 5,980,559; 7,087,073; and 7,749,229; all pending)

## V. Patent Owner's Perspective

What can Patent Owners do to strengthen patents against IPR petitions?

- Include multiple “picture claims” of varying scope
- Include a large number of claims
- Maintain pending continuations

- In our initial 7-part webinar series titled “Challenging Patent Validity in the USPTO,” we explored details regarding several of the post grant tools, with 3 sessions dedicated to Inter Partes Review (IPR), and a final session walking through several hypotheticals, to help listeners understand how these apply to common situations.
- Audio and slides for these webinars are posted online at:  
<http://fishpostgrant.com/webinars/>
- If you listen to these webinars, you will be well positioned to engage in a conversation over whether and when to use those tools and how to defend against them.

## Resources

- F&R 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/>
- USPTO sites:
  - AIA Main: [http://www.uspto.gov/aia\\_implementation/index.jsp](http://www.uspto.gov/aia_implementation/index.jsp)
  - Inter Partes: [http://www.uspto.gov/aia\\_implementation/bpai.jsp](http://www.uspto.gov/aia_implementation/bpai.jsp)

Questions?

#fishwebinar



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