

Post-Grant for Practitioners

Recent Developments in Bio-Pharma



Dorothy Whelan
Principal
Post-Grant Practice Co-Chair
Twin Cities



Gwilym Attwell
Principal
Delaware

Agenda

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- I. Overview of Webinar Series
- II. Statistics
- III. Update re New Rule Changes
- IV. NPE's as Petitioners
- V. Objective Evidence of Nonobviousness
- VI. Biosimilars and Biologics
- VII. Post-Grant Resources

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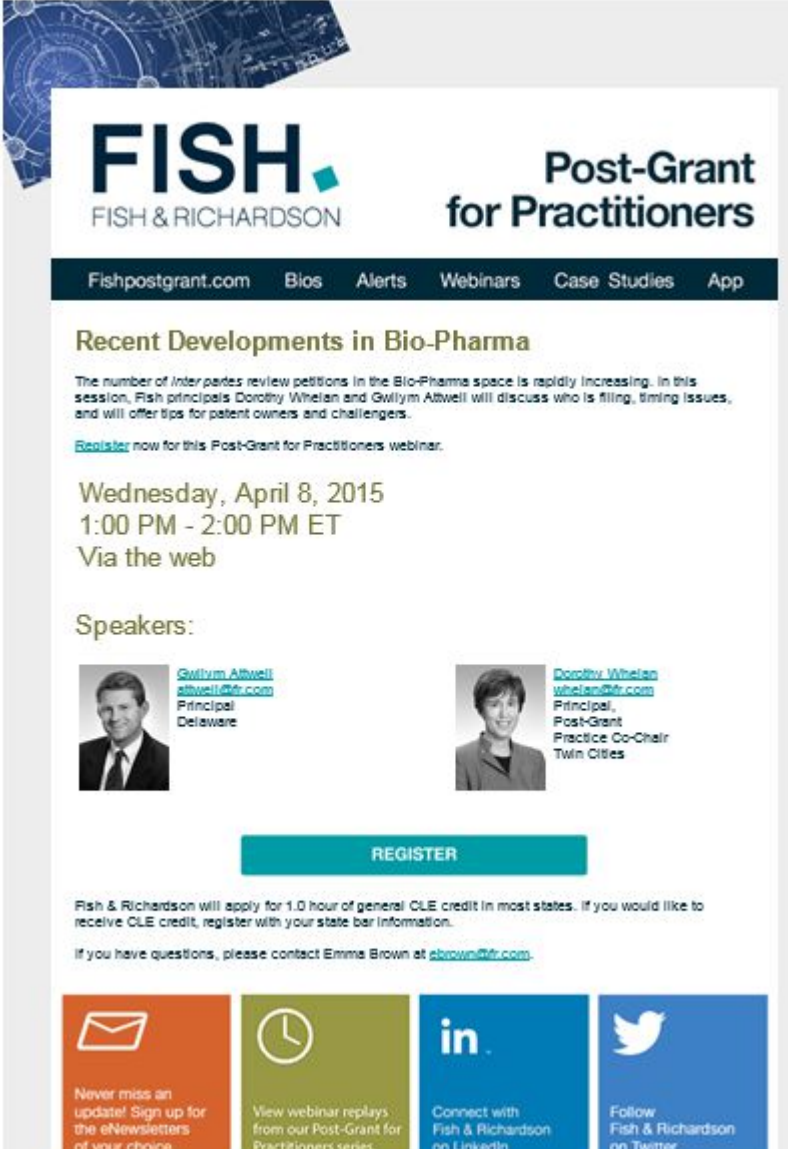
Overview of Webinar Series

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Overview

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- 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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Fishpostgrant.com Bios Alerts Webinars Case Studies App


Recent Developments in Bio-Pharma


The number of *Inter partes* review petitions in the Bio-Pharma space is rapidly increasing. In this session, Fish principals Dorothy Whelan and Gwilym Atwell will discuss who is filing, timing issues, and will offer tips for patent owners and challengers.

[Register](#) now for this Post-Grant for Practitioners webinar.

Wednesday, April 8, 2015
1:00 PM - 2:00 PM ET
Via the web

Speakers:

 [Gwilym Atwell](mailto:atwell@fr.com)
atwell@fr.com
Principal
Delaware

 [Dorothy Whelan](mailto:whelan@fr.com)
whelan@fr.com
Principal,
Post-Grant
Practice Co-Chair
Twin Cities

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If you have questions, please contact Emma Brown at ebrown@fr.com.

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Statistics

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Statistics

- **IPR's Filed?**

- **2705** filed through April 2, 2015
- **131** filed in March 2015

- **CBM's Filed?**

- **321** filed through April 2, 2015
- **13** filed in March 2015

- **FWD's on the Merits Issued So Far**

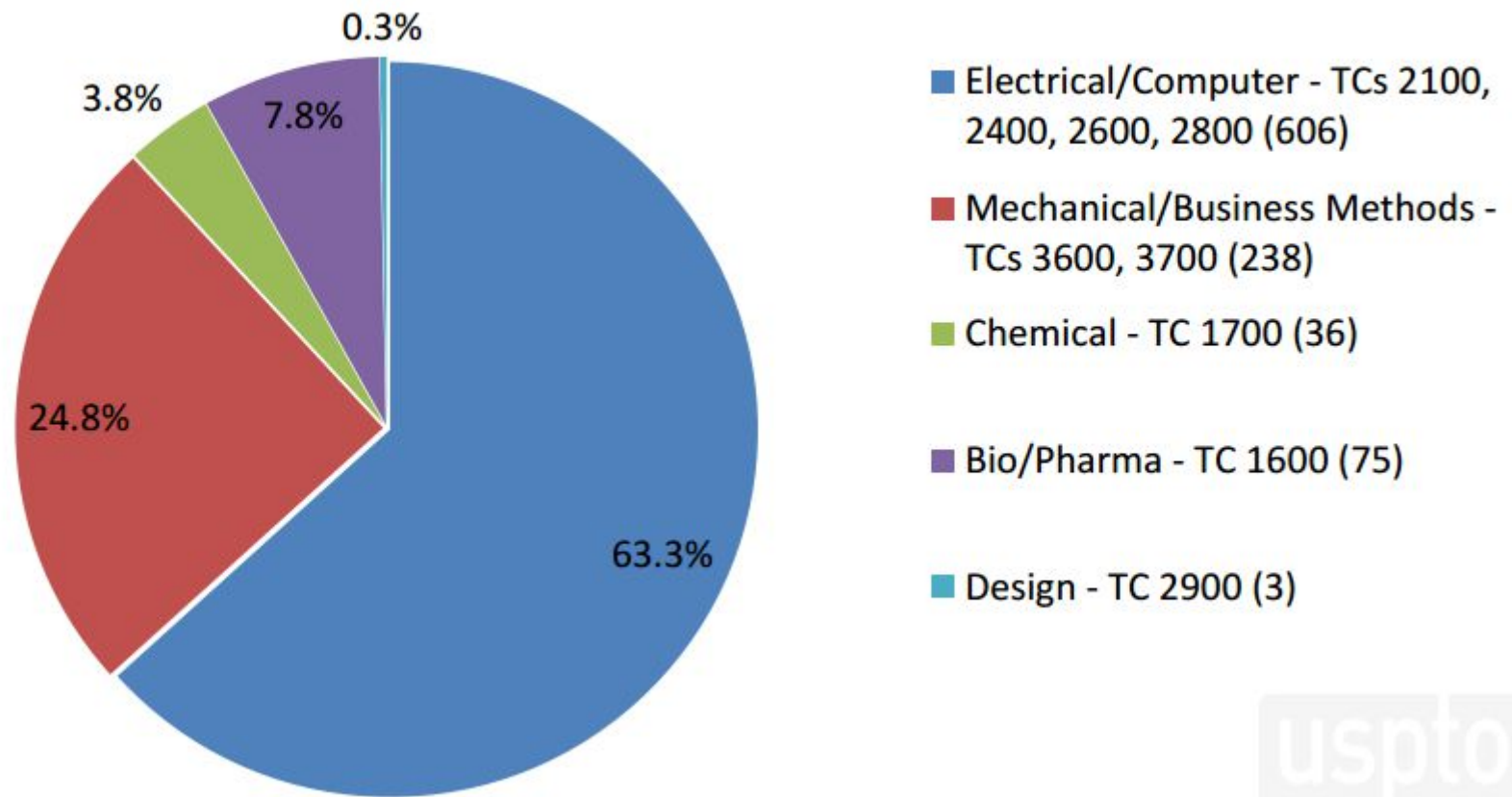
- IPR: **303** through April 2, 2015
- CBM: **41** through March 5, 2015

- **Institution Rate (IPR)**

- FY2013: **87%**
- FY2014: **75%**
- FY2015 to date: **74%**

Statistics (for FY2015 through 4/2/2015)

• AIA Petition Technology Breakdown



Update Regarding Rule Changes

Rule Changes

In a blog post dated March 27, 2015, Director Lee announced a series of new rules packages

Rule Package #1 (“Quick Fixes”)—Effective Immediately:

- Motions to amend: 25 pages plus separate claims appendix
- Petitioner’s reply brief: 25 pages

Rule Package #2—Under Consideration/Late Summer Release:

- Motions to amend, including dispensing with requirement to prove patentability over all relevant art known to patent owner
- Expanding types of evidence that can be submitted in Patent Owner's Preliminary Response
- Clarification of claim construction standard for expired patents
- Adjustments to motions for additional discovery, especially wrt real party in interest
- Multiple proceedings before the PTAB
- Live testimony at oral hearing
- "Rule 11" certification
- Single judge pilot program

NPE's as Petitioners

We are seeing a new breed of petitioners filing IPR petitions in the bio-pharma space

1. “Public interest” groups
2. Financial groups/hedge funds

NPE's as Petitioners

Representative cases:

Initiative for Responsibility in Drug Pricing LLC v. Wyeth, LLC, IPR2014-01259

- Claims covered formulations containing tigecycline (antibiotic)
- Patent was the subject of a separate IPR petition filed by Apotex
- Copycat petition
- Allegedly filed out of concern that Apotex might settle
- Denied—35 U.S.C. § 325(d)

NPE's as Petitioners

Biogatekeeper, Inc. v. Kyoto University, IPR2014-01286

- Claims directed toward stem cells
- Denied—Failure to establish a reasonable likelihood that at least one claim was unpatentable under 35 U.S.C. § 103
- Poor quality petition; no expert declaration

NPE's as Petitioners

Petitions filed by Kyle Bass et al. (hedge funds):

(a) Coalition for Affordable Drugs II LLC v. Acorda Therapeutics LLC, IPR2015-00720; US 8,663,685 [8 claims; all challenged]

- Claims covered formulations of Ampyra® (MS)
- Filed 2/10/15

(b) Coalition for Affordable Drugs II LLC v. Shire, Inc., IPR2015-00988; US 6,773,720 [4 claims; all challenged]

- Claims covered formulations of Lialda® (ulcerative colitis)
- Shire involved in HW litigation against generics involving this drug
- Filed 4/1/15

Petitions filed by Kyle Bass et al. (hedge funds):

(c) Coalition for Affordable Drugs II LLC v. NPS Pharmaceuticals, Inc., IPR2015-00990; US 7,056,886 [75 claims; 20 claims challenged]

- Claims covered formulations of Gattex® (short bowel syndrome)
- NPS previously acquired by Shire, Inc.
- Filed 4/1/15

(d) Coalition for Affordable Drugs III LLC v. Jazz Pharmaceuticals, Inc., IPR2015-01018; US 7,895,059 [16 claims; all challenged]

- Claims covered distribution of Xyrem® (narcolepsy)
- Jazz involved in HW litigation against generics involving this patent
- Filed 4/6/15
- Patent also subject of IPR2015-00548 (filed 1/8/2015 by Par Pharmaceuticals; pending)

NPE's as Petitioners – Motives?

Accorda Therapeutics



Shire Pharmaceuticals



Jazz Pharmaceuticals



NPE's as Petitioners – Motives?

Ampyra® – 4 additional patents listed in Orange Book:

5,540,938- expires 7/30/2018; 8,440,703- expires 4/8/2025

8,354,437- expires 12/22/2026; 8,007,826- expires 5/26/2027

Lialda® – no additional patents listed in Orange Book

Gattex® – 2 additional patents listed in Orange Book:

5,789,379- **expired** 4/14/2015; 7,847,061- expires 11/1/2025

Xyrem® – 14 additional patents listed in Orange Book:

6,780,889- expires 7/4/2020; 7,262,219- expires 7/4/2020

7,668,730- expires 6/16/2024; 7,765,106- expires 6/16/2024

7,765,107- expires 6/16/2024; 7,851,506- expires 12/22/2019

8,263,650- expires 12/22/2019; 8,952,062- expires 12/22/2019

8,324,275- expires 12/22/2019; 8,457,988- expires 12/17/2022

8,589,182- expires 12/17/2022; 8,731,963- expires 12/17/2022

8,772,306- expires 3/15/2033; 8,859,619- expires 12/22/2019

NPE's as Petitioners

- What is the petitioners' overall objective?
 - Bass has said publicly that he will not settle
- What should patent owners do?
- If petitioner loses, can it appeal to the Federal Circuit?
- NPE may lack standing to appeal to the Federal Circuit:
 - *Consumer Watchdog v. Wisconsin Alumni Research Foundation*, 753 F.3d 1258 (Fed. Cir. 2014)

Objective Evidence of Nonobviousness

Objective Evidence of Nonobviousness

Interplex Tech., Inc. v. Saint-Gobain Performance Plastics Rencol Ltd., IPR2014-00309, Paper No. 83 (PTAB Mar. 23, 2015)

- Not a bio-pharma case but a rare decision where claims held to be not unpatentable on the basis of objective evidence
- Claims covered improved hard disk assembly having a “flared” tolerance ring
- Patent owner introduced evidence of commercial success and copying

Objective Evidence of Nonobviousness

- Patent Owner included evidence of nexus:
 - Adding flared guide portion caused sales of flared rings to supplant non-flared rings and sales of other “competing technologies;”
 - Successfully rebutted Petitioner’s argument that market dominance due to Patent Owner’s coercion of customers
 - Petitioner admitted that it made flared rings due to customer requests (“These admissions constituted strong evidence that the commercial success is attributable to customer demand for the patent features”)
 - Petitioner did not introduce its own flared ring until Patent Owner achieved success with Patent Owner’s flared ring
 - Petitioner’s commercial product very similar to Patent Owner’s commercial product

Objective Evidence of Nonobviousness

- PTAB found evidence that a POSITA would have been motivated to modify the prior art: “Apart from consideration of the objective indicia of nonobviousness, we determine that the first three Graham factors favor a determination that the challenged claims are obvious.”
- PTAB concluded that claims would not have been obvious on the basis of strong objective evidence of nonobviousness.

Objective Evidence of Nonobviousness

Are there lessons for owners of bio-pharma patents?

- Still may be difficult to establish non-obviousness of formulations
- Copying not as compelling in the HW or biosimilars context

NEVERTHELESS: The decision demonstrates the importance of including objective evidence of nonobviousness if you have it because in the right circumstance, it could help establish that the challenged claims are not unpatentable

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Biosimilars and Biologics

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Biosimilars and Biologics

- Not governed by Hatch-Waxman regulatory scheme
- Attractive option for FTO purposes because faster than district court litigation
- Many patents have claims to formulations or methods of treatment
 - Potentially vulnerable to a § 103 attack
- IPR is particularly advantageous if 112/101 defenses also exist
- Multi-defendant and timing issues often arise

Biosimilars and Biologics

Representative Cases:

A. Rituximab

1. Boehringer Ingelheim Int'l GmbH et al. v. Genentech, Inc. and Biogen Idec, Inc., IPR2015-00415
 - Filed 12/15/14
 - Claims cover methods of treating RA with rituximab + methotrexate
 - Pending
2. Boehringer Ingelheim Intl'l GmbH et al. v. Biogen Idec, Inc., IPR2015-00418
 - Filed 12/15/14
 - Claims cover methods of treating non-Hodgkin's lymphoma with CVP + rituximab
 - Pending
3. Boehringer Ingelheim Int'l GmbH et al. v. Genentech, Inc., IPR2015-00417
 - Filed 12/15/14
 - Claims cover methods of treating RA by i.v. administration of rituximab
 - Pending

Biosimilars and Biologics

Representative Cases:

B. EPO

1. Hospira, Inc. v. Janssen Pharmaceuticals, Inc.,
IPR2013-00365
 - Filed 6/19/2013
 - Claims cover methods of administering EPO
 - Terminated (patent owner statutorily disclaimed challenged claims)

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- 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/>
 - 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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Dorothy Whelan
*Principal, Post-Grant
Practice Co-Chair*
Whelan@fr.com
612-337-2509

Gwilym Attwell
Principal
Attwell@fr.com
302-778-8458

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