July 11, 2018

Post-Grant for Practitioners: BioPharma Patents at the PTAB

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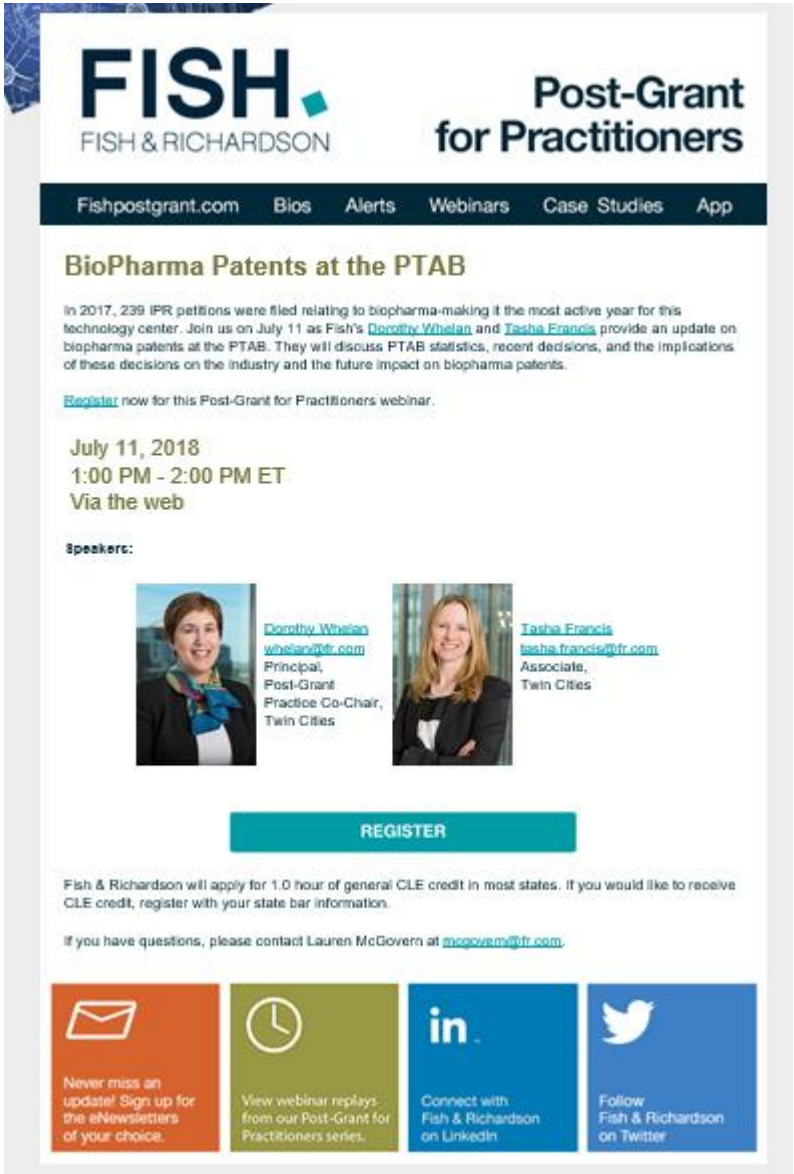
Overview

- How often? … bi-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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BioPharma Patents at the PTAB

In 2017, 239 IPR petitions were filed relating to biopharma-making it the most active year for this technology center. Join us on July 11 as Fish's Dorothy Whelan and Tasha Francis provide an update on biopharma patents at the PTAB. They will discuss PTAB statistics, recent decisions, and the implications of these decisions on the industry and the future impact on biopharma patents.

Register now for this Post-Grant for Practitioners webinar.

July 11, 2018
1:00 PM - 2:00 PM ET
Via the web

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REGISTER

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

If you have questions, please contact Lauren McGovern at mcgovern@fr.com.

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Agenda

- Statistics
- Recent biopharma decisions and case law developments at the PTAB
- What to watch for in 2018

Statistics

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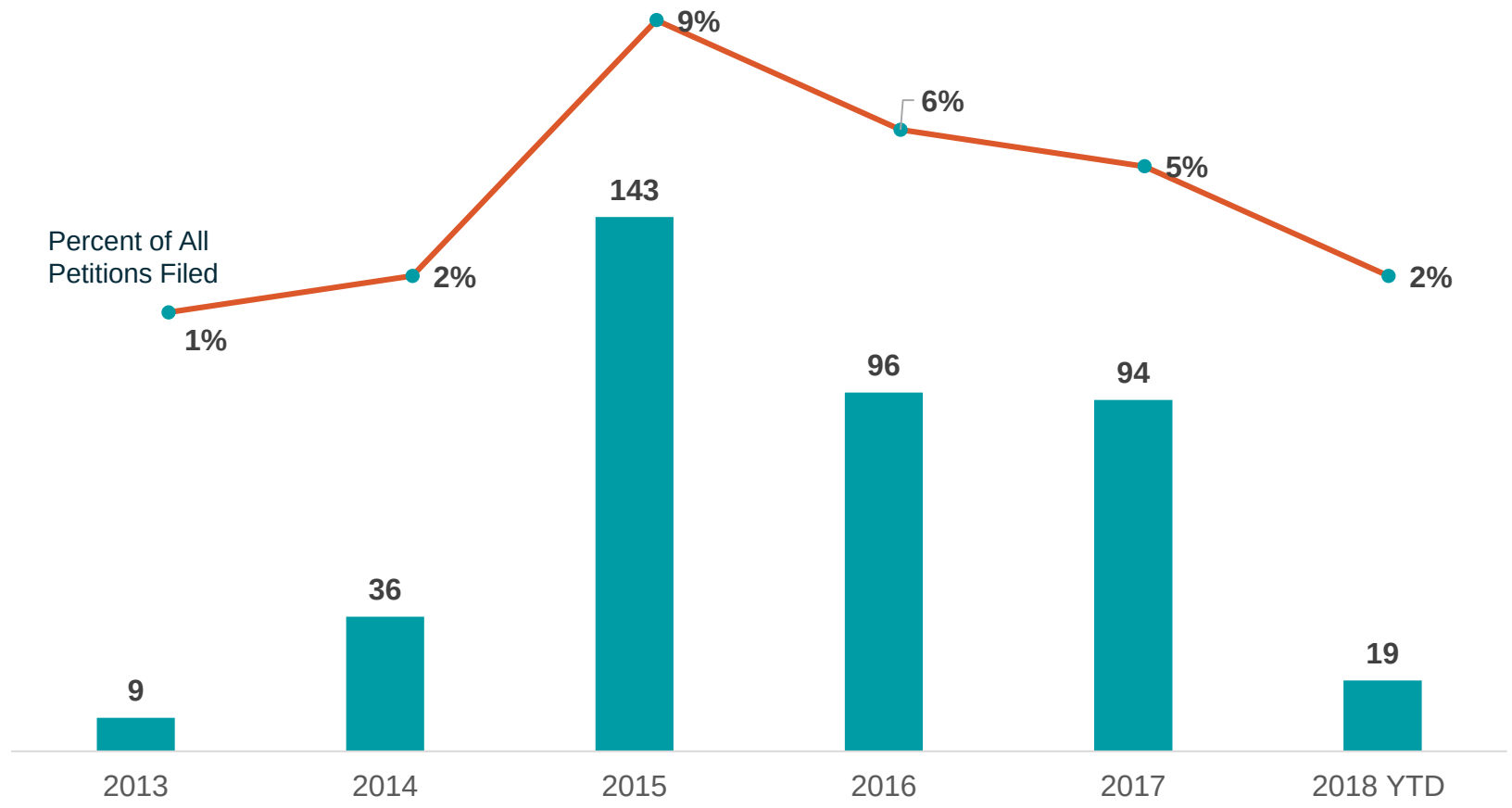
Number of Orange Book Patents Challenged by IPR

Petitions Challenging Orange Book-listed Patents



3 petitions challenging Orange Book-listed patents were filed in CY 2012

Source: Docket Alarm, as of 7/6/2018

Top Petitioners of Orange Book Patents

1. Amneal Pharmaceuticals
2. Apotex
3. Teva Pharmaceuticals
4. Par Pharmaceutical
5. Wockhardt Bio AG
6. Lupin Pharmaceuticals
7. Dr. Reddy's Laboratories
8. Fresenius Kabi
9. Mylan Laboratories
10. Praxair Distribution
11. Akorn
12. Argentum Pharmaceuticals
13. Innopharma Licensing
14. Roxane Laboratories
15. I-Mak
16. Sun Pharma Global Fze
17. Breckenridge Pharmaceutical
18. Glenmark Pharmaceuticals Accord Healthcare

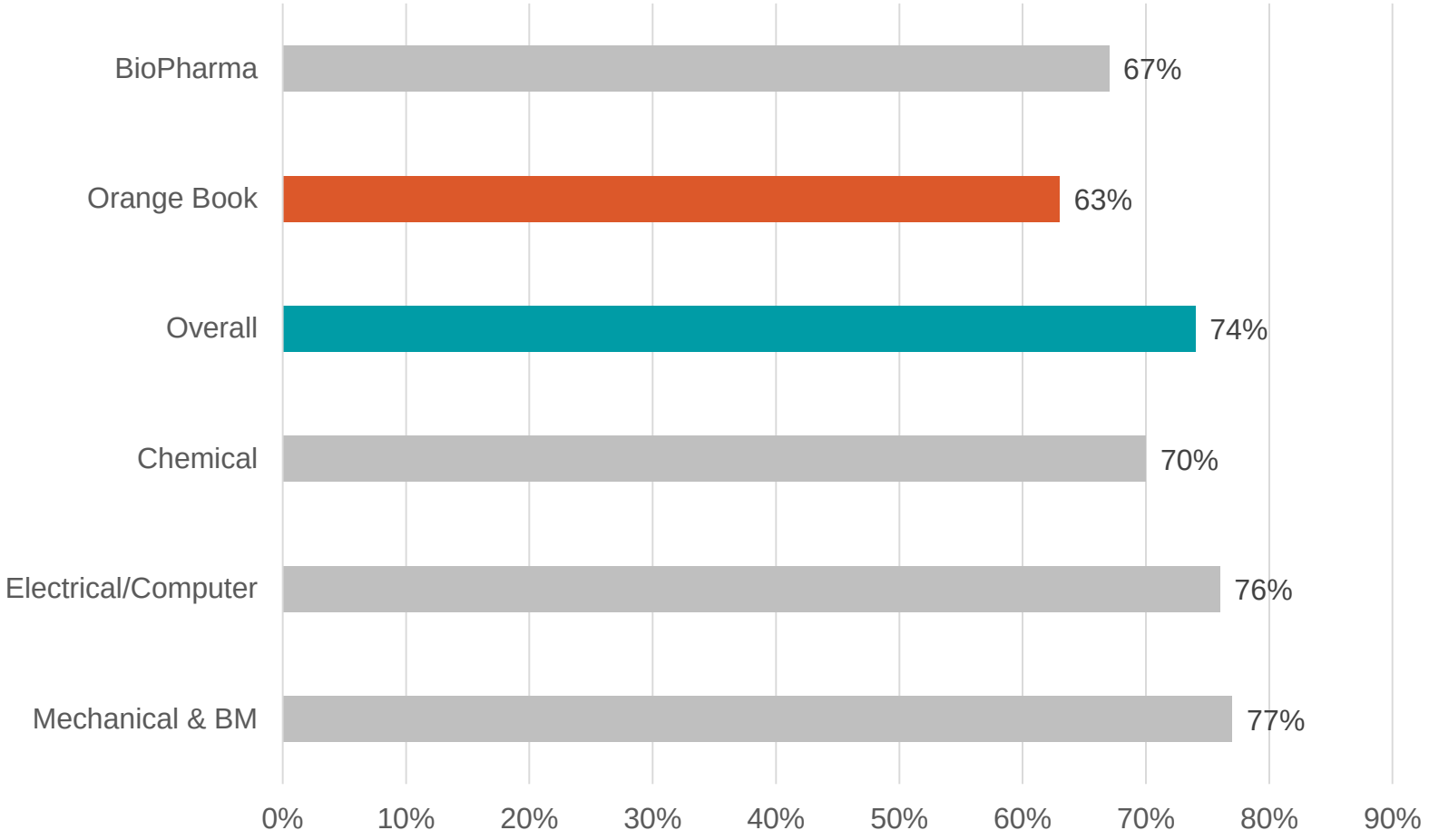
Source: Docket Alarm, as of 7/10/2018

Top Patent Owners of Orange Book Patents

1. Allergan
2. Jazz Pharmaceuticals
3. Novartis AG
4. Astrazeneca
5. Senju Pharmaceutical
6. Eli Lilly and Company
7. Horizon Therapeutics
8. Ino Therapeutics
9. Gilead Pharmasset
10. Pozen
11. Alcon Research
12. Icos
13. Ucb Pharma GMBH
14. Anacor Pharmaceuticals
15. Helsinn Healthcare
16. Hospira
17. Monosol RX
18. Roche Palo Alto
19. Abraxis Bioscience
20. Acorda Therapeutics

Source: Docket Alarm, as of 7/10/2018

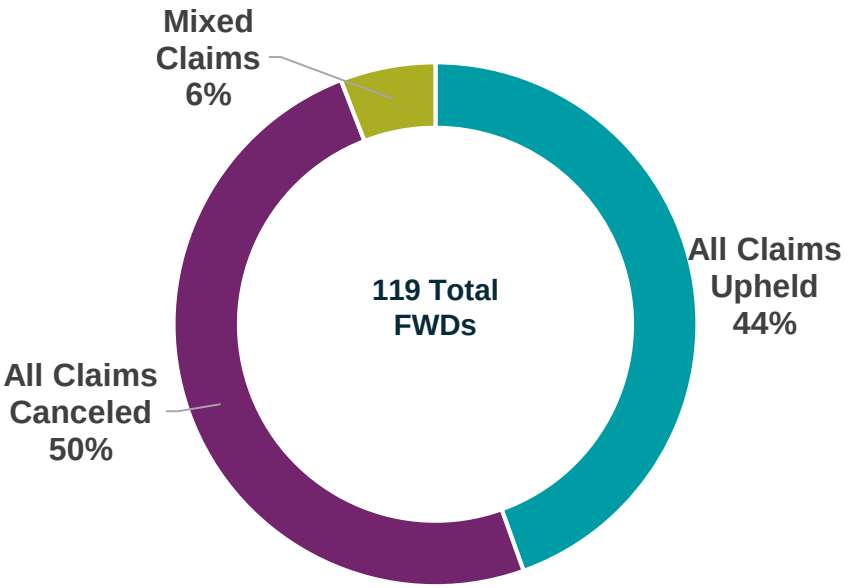
Institution Rates by Technology



Source: Docket Alarm (Orange Book) and Lex Machina, as of 7/6/2018

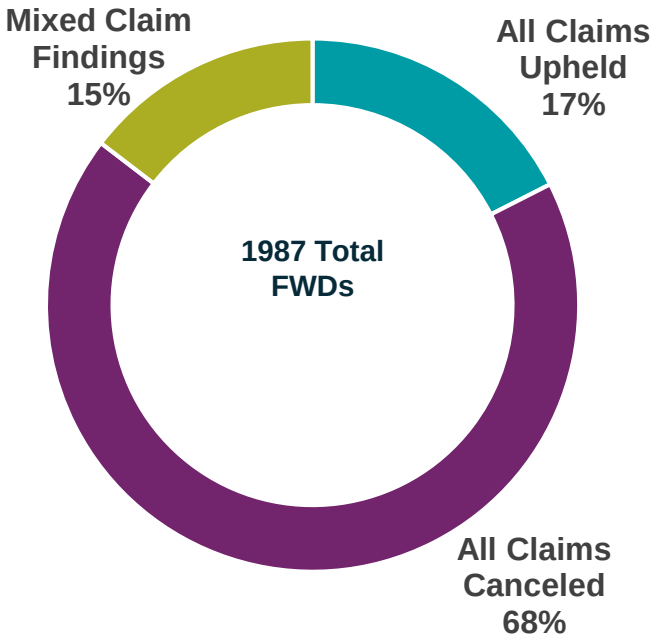
Status of Instituted Claims in FWD

Orange Book-listed Patents



All Other Technologies

Excluding Orange Book-listed Patents



Source: Docket Alarm, as of 7/6/2018

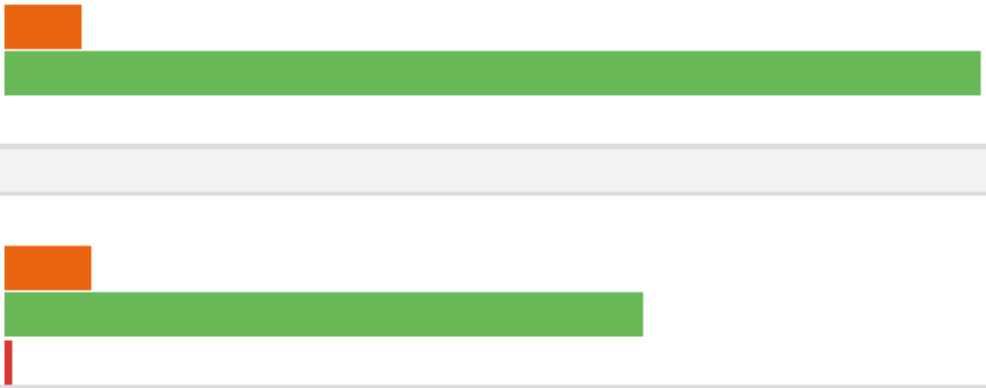
Types of OB Patent Claims Challenged

- Orange Book Patents
  - Method of Treatment Claims
  - Formulation Claims
  - Compound Claims
  - Other Claims
- Process patents and metabolite patents are not listed in the Orange book

Grounds Breakdown for OB Patents at the PTAB

Figure 32: Orange Book Patent PTAB Grounds Breakdown for Trials Terminating in 2016 and 2017

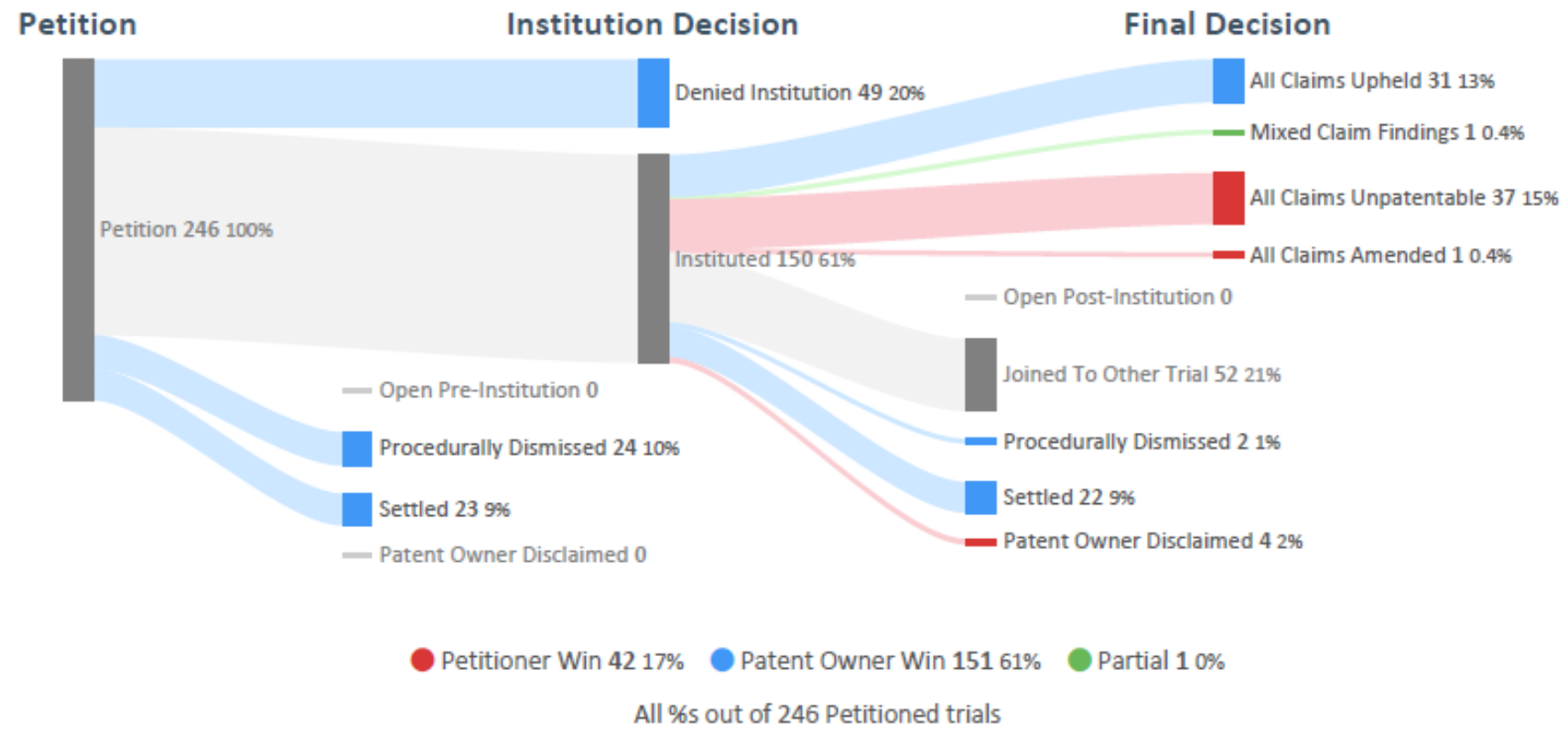
Statute	Trials	Grounds
Institution Decision: Instituted		
§ 101	0	0
§ 102	21	24
§ 103	149	307
§ 112	0	0
Institution Decision: Denied Institution		
§ 101	0	0
§ 102	23	27
§ 103	82	201
§ 112	2	2
Final Decision: Unpatentable		
§ 101	0	0
§ 102	3	4
§ 103	38	74
§ 112	0	0
Final Decision: Upheld		
§ 101	0	0
§ 102	0	0
§ 103	33	60
§ 112	0	0



Source: Lex Machina, Hatch-Waxman ANDA Litigation Report, 2018

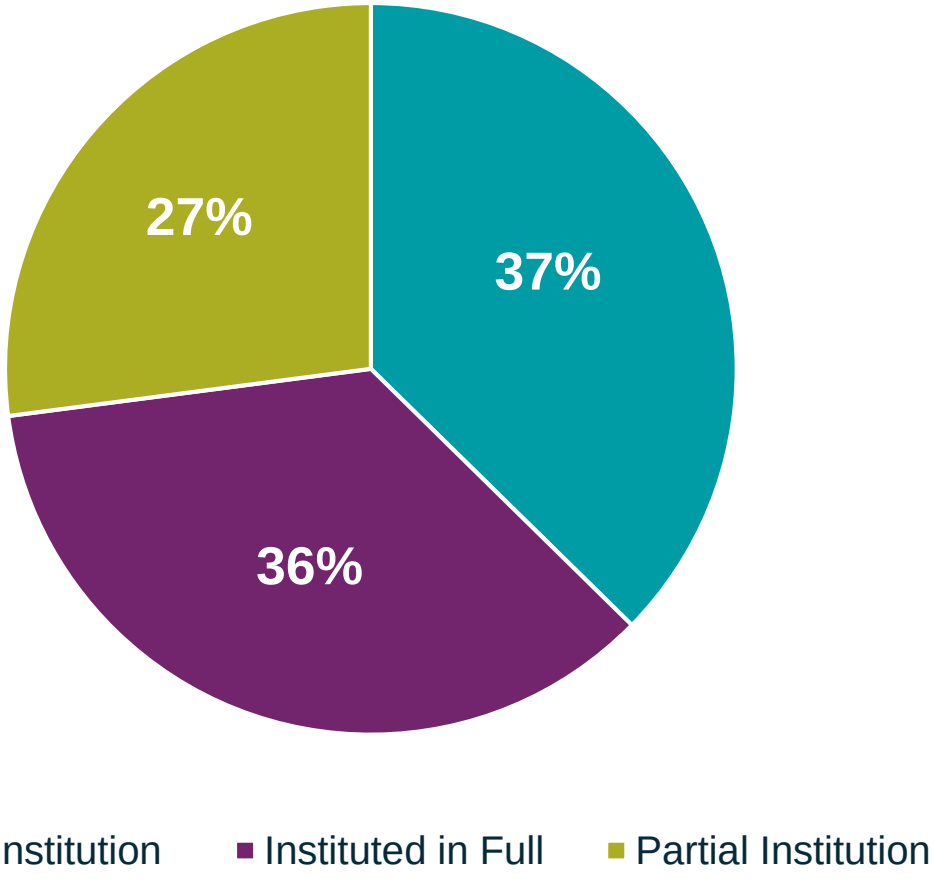
Trial Flow for OB Petitions at the PTAB

Figure 30: Orange Book Patent PTAB Trial Flow for Trials Terminating in 2016 and 2017



Implications of *Oil States* and *SAS* on Orange Book IPRs

- 408 Orange Book related petitions filed through April 24th, 2018
  - Of those, 63% (340) were instituted:



Source: Docket Alarm, as of 6/28/2018

Recent BioPharma Decisions & Case Law Developments at the PTAB

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Proving a Reference is a Printed Publication

***Sandoz Inc. v. AbbVie Biotechnology Ltd.*, IPR2017-01824 (PTAB Feb. 9, 2018)**

- Patent covered a method of treating psoriasis by administering adalimumab (HUMIRA)
- Petitioner relied on the HUMIRA package insert as one of the references in its challenge
- PTAB denied institution because Petitioner failed to prove that the package insert was "publicly accessible to the extent required to establish it as a 'printed publication.'"

Proving a Reference is a Printed Publication

***Sandoz Inc. v. AbbVie Biotechnology Ltd.*, IPR2017-01824 (PTAB Feb. 9, 2018)**

- Legal standard/public accessibility:

"A reference is considered 'publicly accessible' upon a satisfactory showing that the document has been 'disseminated or otherwise made available to the extent that persons interested and ordinarily skilled in the subject matter or art exercising reasonable diligence [ ] can locate it.' …. A party seeking to introduce a reference, therefore, 'should produce sufficient proof of its dissemination or that is has otherwise been available and accessible to persons concerned with the art to which the document relates and thus most likely to avail themselves of its contents.'"

Id., pp. 5-6 (citations omitted).

Proving a Reference is a Printed Publication

***Sandoz Inc. v. AbbVie Biotechnology Ltd.*, IPR2017-01824 (PTAB Feb. 9, 2018)**

- Petitioner, citing an FDA approval letter, asserted that Humira was approved in December 2002 to treat RA and that the package insert was a "prior art FDA approved label" disclosing the RA dosing regimen.
- The package insert contained the date "December 20, 2002" on each of its pages and stated that the insert was "issued" in December 2002.
- Neither of Petitioner's experts addressed whether the package insert was publicly accessible in December 2002.

Proving a Reference is a Printed Publication

***Sandoz Inc. v. AbbVie Biotechnology Ltd.*, IPR2017-01824 (PTAB Feb. 9, 2018)**

- The Board held that Petitioner failed to prove the package insert was publicly accessible for purposes of institution.
- The Board stated that the December 2002 date on the package insert alone was insufficient to establish that the package insert was publicly accessible as of that date.
- The Board noted that Petitioner "does not direct us to any source-identifying information from the FDA (e.g., a copy of the insert on the FDA's website), a publication date, or other indicia indicating when Humira Package Insert, or the information contained therein, became publicly available."
- The Board further noted that Petitioner failed to explain how regulatory approval of Humira in December 2002 evidenced that the package insert was publicly accessible as of that date.
- An FDA approval letter dated December 31, 2002 stated that Humira "will be marketed," indicating that as of December 31, 2002, it had not yet been marketed to the public.

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***Sandoz Inc. v. AbbVie Biotechnology Ltd.*, IPR2017-01824 (PTAB Feb. 9, 2018)**

Take-Away:

- Public accessibility is a potential pitfall for Petitioners and a potential ground for attack by Patent Owners in a preliminary response.
- The package insert or label itself is not enough to show public accessibility as of the critical date. Additional evidence is needed:
  - Evidence showing the package insert or label appeared on the FDA's website as of the critical date.

Proving a Reference is a Printed Publication

***Celltrion, Inc. and Pfizer, Inc. v. Biogen, Inc. and Genentech, Inc.*, IPR2016-01614 (PTAB Feb. 21, 2018)**

- Patent covered a method of treating RA by administering rituximab and methotrexate.
- Petitioners relied on the Rituxan label as part of its obviousness challenge.
- In a final written decision, the Board held that Petitioners failed to prove that the Rituxan label was publicly accessible, and thus qualified as a printed publication. The Board then held that Petitioners failed to prove that the challenged claims were unpatentable.

Proving a Reference is a Printed Publication

***Celltrion, Inc. and Pfizer, Inc. v. Biogen, Inc. and Genentech, Inc.*, IPR2016-01614 (PTAB Feb. 21, 2018)**

- The critical date was May 1998. Petitioners offered several reasons why the label (EX. 1037) was a printed publication.
- First, Petitioners noted that the label bore a copyright date of 1997.
- Second, Petitioners submitted the associated FDA approval letter for Rituxan, and argued that both it and the label were available on the FDA's website as part of the November 26, 1997 approval package for Rituxan. Petitioners further submitted evidence purporting to show that FDA regulations required Genentech to include the label with the Rituxan product in December 1997 when Genentech began selling the product in the United States.

Proving a Reference is a Printed Publication

***Celltrion, Inc. and Pfizer, Inc. v. Biogen, Inc. and Genentech, Inc.*, IPR2016-01614 (PTAB Feb. 21, 2018)**

- The Board stated that the copyright date alone was not evidence that the label was publicly accessible on that date.

- The Board also found that Petitioners failed to prove that the Rituxan label it retrieved from the FDA website in 2016 in preparing the petition was available on the website prior to the critical date in a manner that a POSA could have located it through exercise of reasonable diligence.

Proving a Reference is a Printed Publication

***Celltrion, Inc. and Pfizer, Inc. v. Biogen, Inc. and Genentech, Inc.*, IPR2016-01614 (PTAB Feb. 21, 2018)**

- The Board further dismissed Petitioners' argument that EX. 1037 was part of the FDA approval package and was required to be disseminated to the public with the sale of Rituxan in December 1997:

"In particular, Petitioners have not submitted documentary or testimonial evidence establishing that Exhibit 1037 is, in fact, the drug label disseminated with Rituximab at any time. At most, Petitioner has shown that a drug label was disseminated with Rituximab sales beginning in 1997, while inviting us to speculate as to whether Exhibit 1037 is a copy of that disseminated label." *Id.* at 16.

- Patent Owner had argued that Petitioners failed to submit evidence showing that the FDA regulation on which Petitioners relied prohibited Genentech from making changes to the label before selling the label or that the FDA did not approve a revised label for Rituxan before it was sold.

Proving a Reference is a Printed Publication

***Celltrion, Inc. and Pfizer, Inc. v. Biogen, Inc. and Genentech, Inc.*, IPR2016-01614 (PTAB Feb. 21, 2018)**

- In an unusual twist, the Board authorized Petitioners to serve a request for admission on Patent Owners, asking them to admit that EX. 1037 was a true and correct copy of the Rituxan label included with the sales of Rituxan before May 7, 1999.

- Genentech denied the request and Biogen denied on the ground it lacked sufficient information or knowledge.

Proving a Reference is a Printed Publication

***Celltrion, Inc. and Pfizer, Inc. v. Biogen, Inc. and Genentech, Inc.*, IPR2016-01614 (PTAB Feb. 21, 2018)**

- Petitioners also tried a different tack. Petitioners argued that even if Genentech did not market Rituxan with EX. 1037, a copy of the label was posted on Genentech's website as early as January 23, 1998.
- To support its assertion, Petitioners submitted EX. 1055, a webpage copy of the full prescribing information for Rituxan with a www.gene.com footer bearing the January 23, 1998 date, plus a declaration (EX. 1056) from the office manager from Internet Archives. The declaration included a webpage copy of the label posted on the webpage as of January 23, 1998.
- Petitioners further asserted that Genentech's website was organized such that the label could be easily located.

Proving a Reference is a Printed Publication

***Celltrion, Inc. and Pfizer, Inc. v. Biogen, Inc. and Genentech, Inc.,* IPR2016-01614 (PTAB Feb. 21, 2018)**

- The PTAB considered whether the webpage, including the prescribing information (EX. 1055), was a printed publication. However, the PTAB found that it was not because the Petitioners failed to submit evidence supporting their allegation that Genentech's website would have permitted a POSA to locate EX. 1055:

"That assertion is not further explained or accompanied by citation to any evidence supporting Petitioners' contention about Genentech's website. Nor have Petitioners offered evidence indicating that persons interested and ordinarily skilled in treating rheumatoid arthritis would have identified and visited Genentech's website before the critical date, and in doing so, would have searched for rituximab drug information, a product newly manufactured and indicated for the treatment of non-Hodgkin's lymphoma …. Petitioners have not submitted any supporting evidence for us to consider regarding the issue of whether Ex. 1055 would have been, for example, 'indexed and thereby findable by an internet search engine.' …. Rather, Petitioners submit only attorney argument that 'Genentech's website was organized such that the label could be easily located.'"

Id. at 19.

Proving a Reference is a Printed Publication

***Celltrion, Inc. and Pfizer, Inc. v. Biogen, Inc. and Genentech, Inc.*, IPR2016-01614 (PTAB Feb. 21, 2018)**

Take-aways:

- It is very difficult to establish that a label is a printed publication.
- If you are relying on a non-governmental website, make sure you show, likely with an expert declaration, that a POSA would have looked to that site and could have found the label.

What To Watch For

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Proposed Legislation

- Hatch-Waxman Integrity Act
  - Proposed by Senator Hatch (Utah) June 14, 2018
  - Seeks to "to restore the careful balance the Hatch-Waxman Act struck to incentivize generic drug development."
  - Proposes amendments to FD&C Act, BPCIA and federal security regulations requiring generic applicants to certify:
    - (i) neither the applicant nor any party in privity with the applicant ***has filed, or will file, a petition to institute inter partes review or post-grant review*** of that patent …. and
    - (ii) in making the certification required under subparagraph (A), the applicant is not relying in whole or in part on any decision issued by the Patent Trial and Appeal Board in an *inter partes* review or post-grant review ….

Hatch Waxman Integrity Act

- Would require biosimilar applicants to include:
  - with respect to any patent that is, or that could be, included on a list of patents under subsection 18 (*l*)(3)(A)(i), … a certification that neither the applicant nor any party in privity with the applicant ***has filed, or will file, a petition to institute inter partes review or post grant review of that patent*** ….

- Proposes amendments to Securities Exchange Act to:
  - consider a person as using a manipulative or deceptive device if the person (or an affiliate) files a petition to institute an IPR proceeding with respect to a patent and the person (or an affiliate), during a 180-day period spanning 90 days before and 90 days after filing that challenge, ***engages in a short sale of any publicly traded security*** of the owner of the patent that is the subject of the petition.

Post-Grant Resources

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Resources

- Fish websites:
  - 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/
  - Post-Grant Radio: http://fishpostgrant.com/podcasts/
- USPTO sites:
  - AIA Main: http://www.uspto.gov/aia_implementation/index.jsp
  - Inter Partes: http://www.uspto.gov/aia_implementation/bpai.jsp

Post-Grant Radio

Check out our newest Post-Grant Radio Podcast:

https://fishpostgrant.com/podcasts/

July 11 , 2018

Fish Post-Grant Radio: Episode #10: Erika Arner, PTAB Bar Association President

This episode of Fish Post-Grant Radio features Erika Arner, who was appointed as president of the PTAB Bar Association earlier this year. In it, we learn more about the office of the president and what Erika has planned for the future of the PTAB Bar Association.

Thank You!

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