PTAB Pharmaceutical Patent Round Up: Update on Wins, Losses and Appeals

Pearl Siew
Senior Vice President
Intellectual Property
Eagle Pharmaceuticals, Inc.

Joshua Davis
Partner
Reed Smith LLP

Laura Lydigsen
Shareholder
Brinks Gilson & Lione

Gregory Morris, Ph.D.
Partner
Honigman Miller Schwartz and Cohn LLP

Stephen C. Stout
Partner
Vinson & Elkins LLP

Tweeting about this conference?

#ACIPIV
PTAB Statistics
854 Total AIA Petitions in FY17 (Technology Breakdown)

Source: Patent Trial and Appeal Board Statistics (Feb. 28, 2017)
Technology Center 1600 (TC1600) covers biotechnology and organic chemistry.

Source: M. Grewal, J. Hill, and K. Zalewski, “Trends in Inter Partes Review of Life Sciences Patents,” 92 BNA’s Patent, Trademark & Copyright Journal 3 (June 17, 2016)
Number of Patent Owner Preliminary Responses in IPRs by Fiscal Year

Source: Patent Trial and Appeal Board Statistics (Feb. 28, 2017)
Percent of Petitions Instituted (Technology Breakdown)

Source: Patent Trial and Appeal Board Statistics (Feb. 28, 2017)
Institution Rates for TC1600

Source: M. Grewal, J. Hill, and K. Zalewski, “Trends in Inter Partes Review of Life Sciences Patents,” 92 BNA’s Patent, Trademark & Copyright Journal 3 (June 17, 2016)
Number of Decisions On Institution Per Fiscal Year By Outcome

Source: Patent Trial and Appeal Board Statistics (Feb. 28, 2017)
IPR Settlements by Fiscal Year

Source: Patent Trial and Appeal Board Statistics (Feb. 28, 2017)
Disposition of IPR Petitions Completed

Source: Patent Trial and Appeal Board Statistics (Feb. 28, 2017)
IPR Petitions Terminated

Source: Patent Trial and Appeal Board Statistics (Feb. 28, 2017)
Trial Outcomes for Instituted Claims (Technology Breakdown)

Data includes IPR and CBM trial outcomes. Claims involved in instituted trials that settle or are dismissed are not depicted. Accordingly, a bar may not add up to 100%.

Source: Patent Trial and Appeal Board Statistics (Feb. 28, 2017)
Invalidation Rates for TC1600

Source: M. Grewal, J. Hill, and K. Zalewski, “Trends in Inter Partes Review of Life Sciences Patents,” 92 BNA’s Patent, Trademark & Copyright Journal 3 (June 17, 2016)
IPRs Filed Through Mar. 16, 2016

Total: 4,253

OB-Listed
IPRs, 228
(5.36%)

Non-OB
Listed
IPRs, 4,025
(94.63%)

Source: Prof. Jacob Sherkow of New York Law School at BIO IPCC Spring 2016 Meeting
OB IPRs By Type

- **Brand Manufacturers**: 37 (16.22%)
- **Investment Firms**: 37 (16.22%)
- **Public Interest Org.**: 2 (0.88%)
- **Generic Manufacturers**: 152 (66.67%)

Total: 228

Source: Prof. Jacob Sherkow of New York Law School at BIO IPCC Spring 2016 Meeting
OB IPRs By Status

- Instituted, 98 (42.9%)
- Not Instituted, 68 (29.8%)
- Pending, 52 (22.8%)
- Settled (Pre-Institution), 10 (4.3%)

Total: 228

Source: Prof. Jacob Sherkow of New York Law School at BIO IPCC Spring 2016 Meeting

#ACIPIV
Expert Q&A on Recent Developments with Orange Book-Listed Patent Challenges at the PTAB (August 2016), Practical Law Intellectual Property & Technology

OB Institution Statistics

Source: PTAB docket through Aug. 5, 2016.

OB Final Written Decision Statistics

Source: PTAB docket through Aug. 5, 2016.  

Expert Q&A on Recent Developments with Orange Book-Listed Patent Challenges at the PTAB (August 2016), Practical Law Intellectual Property & Technology
Drugs Facing IPR Challenges

- Adderall (pending)
- Alimta (instituted)
- Ampyra (instituted)
- Cialis (unpatentable)
- Copaxone (instituted)
- Cubicin (unpatentable)
- Emend (not instituted)
- Eliquis (not instituted)
- Faslodex (pending)
- Inomax (not instituted)
- Jevtana Kit (instituted)
- Kerydin (instituted)
- Onglyza (instituted)
- Opana (patentable)
- Oxycontin (pending)
- Pazeo (instituted)
- Restasis (pending)
- Revlimid (unpatentable)
- Suboxone (unpatentable; pending)
- Tarceva (pending)
- Tecfidera (instituted)
- Toviaz (instituted)
- Tygacil (patentable)
- Vimpat (instituted)
- Xyrem (unpatentable)
- Zortress (instituted)
Parallel Proceedings
What can you do to have the best chance?
Choose Experts, Vet Arguments Early

IPR Expert List
1.
2.
3.
Give Proper Attention to Witness Preparation
Motions to Amend
Two Kinds of Motions to Amend Are Allowed By Statute

“(1) During an inter partes review instituted under this chapter, the patent owner may file 1 motion to amend the patent in 1 or more of the following ways:

   (A) **Cancel** any challenged patent claim.

   (B) For each challenged claim, propose a reasonable number of **substitute** claims.

   * * * * *

(3) SCOPE OF CLAIMS. – An amendment under this subsection may not enlarge the scope of the claims of the patent or introduce new matter.”

35 U.S.C. § 316(d)
Three PTAB Decisions Illustrate Framework for Motions to Amend


*Shinn Fu Co. of Am. v. The Tire Hanger Corp.*, Case IPR2015-00208 (PTAB Apr. 22, 2016) (Paper 24)
Idle Free

• Board dismissed motion to amend because patent owner filed the motion without first conferring with the Board, but the Board nonetheless issued an opinion discussing requirements for a motion to amend.

• “Congress provided an opportunity for a patent owner to file a motion to amend . . . but did not intend that opportunity to be unfettered.”

• “An inter partes review is a focused proceeding, unlike ex parte patent prosecution or patent reexamination.”

• Challenged claims can generally be replaced by only one proposed substitute claim, and patent owner must identify the claim to be replaced.

• “The burden is not on the petitioner to show unpatentability, but on the patent owner to show patentable distinction over the prior art of record and also prior art known to the patent owner.”
MasterImage 3D

• Order setting due date for Patent Owner’s Motion to Amend. “[W]e take this opportunity to make three points of clarification regarding . . . Idle Free.”

• Idle Free’s “prior art of record . . . should be understood as referring to: a. any material art in the prosecution history of the patent; b. any material art of record in the current proceeding, including art asserted in grounds on which the Board did not institute review; and c. any material art of record in any other proceeding before the Office involving the patent.”

• Idle Free’s “prior art known to the patent owner . . . should be understood as no more than the material prior art that the Patent Owner makes of record in the current proceeding pursuant to its duty of candor and good faith.”

• “With respect to a motion to amend, once Patent Owner has set forth a prima facie case of patentability of narrower substitute claims over the prior art of record, the burden of production shifts to Petitioner.”
Shinn Fu

Claims at issue were directed to a method to temporarily retain a vehicle wheel.
Shinn Fu

• Final written decision, holding challenged claims unpatentable and granting motion to amend.

• “Although not required to prove that the claims are patentable over every piece of prior art known to a skilled artisan, a patent owner is required to explain why the claims are patentable over the prior art of record.”

• “In addition, [the patent owner’s] duty of candor and good faith . . . requires that it address not only prior art of record but also any relevant prior art known to it.”

• “There is, however, no requirement that a patent owner analyze expressly every individual reference cited during prosecution of the challenged patent, particularly where, as here, there are many different permutations of the cited prior art. A patent owner meets its duty of candor and good faith by grouping prior art references together according to their particular teachings without having to make a presentation on each and every reference giving rise to that same teaching.”
Outcomes of 118 Decided Motions to Amend Requesting Substitute Claims

- **Granted**: 2
- **Granted-In-Part**: 4
- **Denied**: 112

Source: PTAB Motion to Amend Study, April 30, 2016
Reasons Given for Denials of Motions to Amend

- Ineligible Subject Matter
- Written Description
- Broadening
- 102/103
- Multiple
- Procedural

24 of 27 involve 102/103

Source: PTAB Motion to Amend Study, April 30, 2016
Are the Tides Turning for Motions to Amend Claims in IPR Proceedings?

By Jo Dale Carothers on April 13th, 2017

Posted in Patent Law

PTAB Update -- Shire Has Rare Motion to Amend Granted

By Andrew Williams

Shire’s Granted Motion to Amend Offers Additional Insight Into PTAB Amendment Practice

Wednesday, April 5, 2017

PTAB Grants Motion to Amend Claims, Kind Of

by Patrick Elsevier | Apr 7, 2017 | Amendment Practice, Pharmaceutical
Amerigen

• Shire filed a motion to amend cancelling certain instituted claims and to substitute a claim for an instituted claim. The substitution eliminated dependencies to instituted (and cancelled) claims.

25. The pharmaceutical composition of any one of claims 2, 13 or 18 to 20 wherein the pharmaceutically active amphetamine salt in (a) and (b) comprises mixed amphetamine salts.

26. The pharmaceutical composition of any one of claims 2[[,]] or 13 or 18 to 20 wherein the pharmaceutically active amphetamine salt in (a) and (b) comprises mixed amphetamine salts.⁴

• “[T]he practical effect of [the substitution] would be to leave no instituted claim remaining in the trial.”
**Amerigen**

- Amerigen opposed the substitution because Shire had not established the patentability of claim 26 over the prior art as required by *Idle Free*.

- Board explained that the substitution “has the effect of eliminating three claims dependent on instituted claims 18-20, and preserving to claims dependent from non-instituted claims 2 and 13.”

- “[E]ffectively, no claim is being amended, and claims are only being cancelled” and that “there is no requirement for Shire to prove . . . that original non-amended claims are patentable over all potential prior art, especially non-instituted claims.”

- Board granted the amendment.

*Amerigen Pharm. Ltd. v. Shire LLC, Case IPR2015-02009 (PTAB Mar. 31, 2017) (Paper 38)*
In re Aqua Prods., Inc.

• May 2016, a Federal Circuit panel affirmed a PTAB decision denying a motion to amend. “Our precedent has upheld the Board’s approach of allocating to the patentee the burden of showing that its proposed amendments would overcome the art of record.”


• The Federal Circuit is reviewing whether the PTO may require the patent owner to bear the burden of persuasion or a burden of production regarding patentability of the amended claims as a condition of allowing them.
Notable Cases
Recent decisions related to PTAB proceedings that are of particular importance for the pharmaceutical and biotech industries:

**Inter Partes Review**

**Post Grant Review**

- Inter Partes Review of U.S. Patent No. 8,337,856, directed to antibody conjugates and pharmaceutical compositions useful in the treatment of cancer.

- Involved Parties
  - ImmunoGen – assignee of the ’856 patent.
  - Genentech – worldwide exclusive licensee of ’856 patent and manufacturer of Kadcyla®.
  - Phigenix – patent portfolio manager with rights to U.S. Patent No. 8,080,534, which Phigenix claims also covers Genentech’s activities related to Kadcyla®.

- Background
  - Genentech refused to license the ’534 patent from Phigenix.
  - Phigenix sued Genentech in district court for infringement of the ’534 patent.
  - Phigenix also petitioned for review of the ’856 patent via IPR.
PTAB Pharmaceutical Patent Invalidity Round-Up

• *Phigenix, Inc. v. ImmunoGen, Inc.*, 845 F.3d 1168 (Fed. Cir. 2017).
  
  • **Outcome**
    
    • PTAB upheld the challenged claims of the ’856 patent.
    
    • Phigenix appealed, but the Federal Circuit determined that Phigenix did not have standing to maintain the appeal because there was no injury-in-fact:
      
      • No risk of infringement.
      
      • Not a licensee.
      
      • Potential loss of licensing revenue from ’534 patent due to ’856 patent too tenuous to satisfy injury-in-fact requirement.
  
  • **Implications**
    
    • Appeal of PTAB decisions will be largely unavailable to certain types of petitioners absent very specific circumstances.
    
    • Party seeking appeal from PTAB proceedings will be allowed to supplement record with evidence supporting standing if no such evidence developed below.
PTAB Pharmaceutical Patent Invalidity Round-Up

  - Inter Partes Review of U.S. Patents Nos. 6,316,023 and 6,335,031, both directed to pharmaceutical compositions useful in the treatment of Alzheimer’s disease.
  - Background
    - Novartis asserted the '023 and '031 patents against several generic companies in district court litigation.
    - Validity of the patents was upheld by both the U.S. District Court for the District of Delaware and the Court of Appeals for the Federal Circuit:
      - **Novartis Pharm. Corp. v. Watson Labs., Inc.,** 611 F. App’x 988 (Fed. Cir. 2015).
  - Timeline Related to Novartis/Noven
    - April 2, 2014 – Noven files IPR petitions.
    - June 2, 2015 – Oral hearing in IPRs.
    - Sept. 28, 2015 – Final written decision in IPRs finding patents invalid.

  • **Outcome**
    • Noven challenged the ’023 and ’031 patents based on similar evidence and arguments in both the district court and IPRs.
    • Novartis argued that the district court’s finding of validity (and the Federal Circuit’s previous affirmance of validity on similar grounds in the Watson case) precluded a different result in the IPRs.
    • Federal Circuit disagreed:
      • “As an initial matter, the record here differed from that in the prior litigation, meaning that Novartis’s argument rests on a faulty factual predicate.”
      • “Nevertheless, even if the record were the same, Novartis’s argument would fail as a matter of law.”
    • Preponderance of the evidence (PTAB) v. clear and convincing (district court).

  • **Implications**
    • Patent owners cannot rely solely on previous district court determinations of validity.
    • Another area of the law where courts have recognized and approved of differing standards in district court litigation versus proceedings before the PTAB.
PTAB Pharmaceutical Patent Invalidity Round-Up

  • Post Grant Review of U.S. Patent No. 8,859,623, directed to methods of using stabilized ophthalmic formulations of phenylphrine hydrochloride to dilate pupils.

• Background
  • Altaire manufactured and sold ophthalmic formulations that it contends satisfy the ’623 for several years before the filing of the application that led to the ’623 patent.
  • Altaire and Paragon entered into an agreement in 2011 regarding further development of the market for phenylphrine hydrochloride formulations.
  • In 2013, Paragon filed the patent application that led to the ’623 patent.
  • The ’623 patent lists only Paragon employees as inventors and Paragon as the sole assignee.
  • Altaire petitioned for Post Grant Review of the ’623 patent, and recently (March 31, 2017) filed suit in district court seeking declaratory judgements of invalidity and/or unenforceability of the ’623 patent, or in the alternative, a correction to inventorship.

• Importance
  • First pharmaceutical patent to undergo Post Grant Review through a final written decision.
PTAB Pharmaceutical Patent Invalidity Round-Up

  - **Outcome**
    - PTAB instituted review only on grounds that the ’623 patent was obvious over products sold by Altaire before the effective filing date.
    - Altaire failed to demonstrate obviousness because its original petition did not satisfy 37 CFR § 42.65(b):
      - “If a party relies on a technical test or data from such a test, the party must provide an affidavit explaining:
        - (1) Why the test or data is being used;
        - (2) How the test was performed and the data was generated;
        - (3) How the data is used to determine a value;
        - (4) How the test is regarded in the relevant art; and
        - (5) Any other information necessary for the Board to evaluate the test and data.”
    - Attempts to rectify these deficiencies in Altaire’s reply were rejected.
  - **Implications**
    - Similar to what have seen from PTAB in IPR decisions.
    - Strict adherence to rules, and very little opportunity to correct mistakes/deficiencies.
Update on Reverse Patent Trolls