Post-Grant Review:
Challenging the Validity of Patents

Partner Firms:

Buchanan Ingersoll & Rooney PC

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Erin M. Dunston
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Consistently ranked among the top intellectual property firms in the nation and worldwide, Knobbe Martens has over 275 lawyers and scientists nationwide and dedicates its practice to all aspects of intellectual property and technology law, including litigation. Knobbe Martens serves a diverse group of clients from multinational corporations to emerging businesses of all stages. The firm is headquartered in Orange County, California, with offices in Los Angeles, New York, San Diego, San Francisco, Seattle, Silicon Valley and Washington, D.C., and enjoys an international reputation for excellence. More information about the firm can be found at www.knobbe.com.

Post-Grant Review: Challenging the Validity of Patents

Brief Speaker Bios:

BUCHANAN INGERSOLL & ROONEY PC
Erin M. Dunston
Shareholder

Erin M. Dunston is the Biotechnology practice group leader of Buchan Ingersoll & Rooney's Intellectual Property section and a member of the firm's Associates Committee. She focuses on disputes before the Patent Trial and Appeal Board, district court litigation, opinions, and prosecution — primarily in the fields of biotechnology, pharmaceuticals, and medical devices. Her district court litigation practice includes classic infringement and declaratory judgment cases, as well as Paragraph IV cases.

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Partner

Kerry S. Taylor, Ph.D. is a Partner in the Knobbe Martens San Diego office, practicing intellectual property law since 1998 in areas including Inter Partes Reviews, patent litigation, patent prosecution, strategic planning and counseling relating to infringement and licensing issues, and IP due diligence studies. Kerry is very active in the firm's post-grant practice and serves as the chief editor of the firm's PTAB blog (https://www.knobbe.com/blog/ptab). He received his doctorate degree in biochemistry and molecular biology from the University of Chicago and was awarded the Lucille P. Markey award for his work in the field of structural biology, using primarily x-ray crystallographic techniques to study protein engineering and design. After receiving his doctorate degree, Kerry received his J.D. degree from the University of California – Berkeley School of Law.

Post-Grant Review: Challenging the Validity of Patents

For the past years, several provisions from the United States Patent and Trademark Office (USPTO) were made to review the validity of granted patents. Due to the changing U.S. patent system, the American Invents Act (AIA) established post-grant reviews to validate patents in a much wider range of invalidity grounds and applications.

However, with the growing number of significant changes brought by the AIA to the U.S. patent system, more issues qualify for PGR and preemptive challenges arise that generally affect the patent landscape. While the validity of patents is still in question, some claims were found out to be invalid and many of these petitions are still pending, raising a heightened concern among the patent owners and companies. With only few among PGR petitions granted, PGR primarily aims to challenge unpatentable claims, review the patentability of such claims on trial proceedings and produce more grounds to challenging the validity of patents.

In this LIVE Webcast, a panel of distinguished professionals and thought leaders brought together by The Knowledge Group will help the audience understand the fundamental aspects of Post-Grant Reviews. They will also provide an in-depth discussion of the challenges in verifying the validity of patents and the best strategies to avoid potential legal risks and threats.

Key topics include:

- An Overview of Post-Grant Review
- PGR Proceedings: Key Issues and Considerations
- Timing and Procedural Considerations for Petitioners and Patent owners in view of SC's upcoming decision in Oil States
- Statutory Grounds Against Patents Claims
- Sovereign Immunity moot all AIA Trials
- Aqua Products and Motions to Amend
- Patent's Validity: Challenging Grounds and Range of Validities
- Patent Eligibility Claims and Judicial Exceptions
- Practice Tips on PGR Petitions
- Trends, Developments and What Lies Ahead

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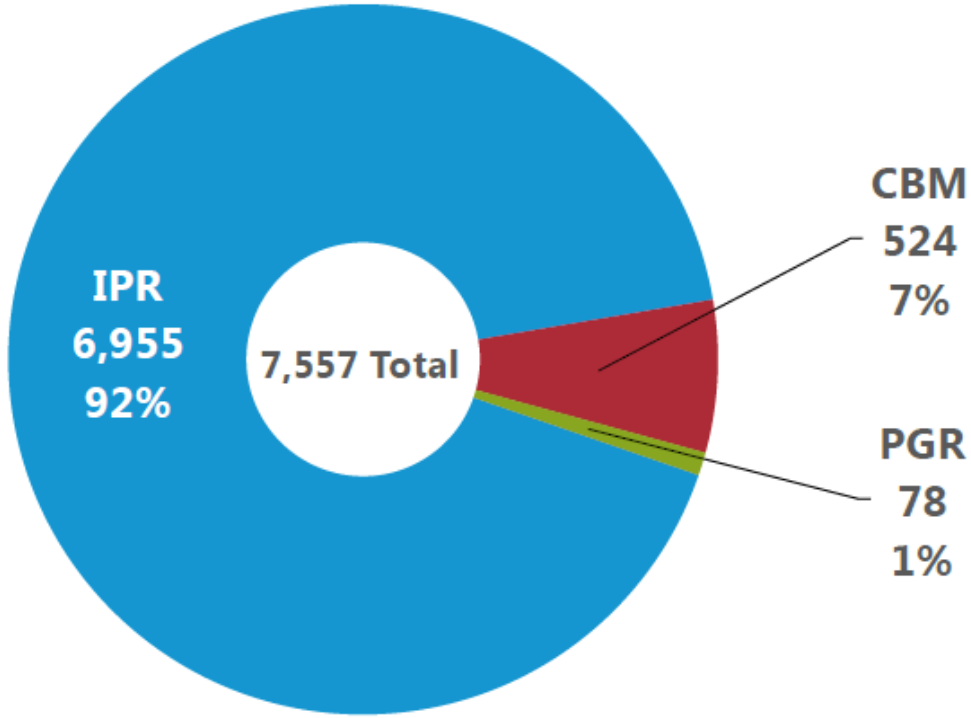
Numbers, Trends, Outcomes

Petitions by Trial Type
(All Time: 9/16/12 to 9/30/17)



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Numbers, Trends, Outcomes

- As of October 31, 2017, 82 PGR Petitions have been filed

Fiscal Year	Number of Petitions Filed
2014	2
2015	11
2016	24
2017	41
2018	4

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Numbers, Trends, Outcomes

Fiscal Year	Petitions Filed	Instituted (%)	Settlements/ Terminations
2014	2	0 (0%) (Both Terminated Prior to Institution)	2
2015	11	10 (91%) (Only 2015-00023 not)	0
2016	24	9 (41%)	2
2017	41 (16 Eligible)	8 (50%)	2
2018	4	N/A	N/A

Numbers, Trends, Outcomes

In The Petitions

Fiscal Year	101	102	103	112 W	112 E	112 I
2014	0	1	1	2	2	2
2015	6	7	10	1	3	3
2016	4	9	21	8	7	6
2017	1	7	49	8	9	8
2018	0	4	20	2	3	6

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Most Successful Bases

In The Petitions/Institution Decision

Fiscal Year	101	102	103	112 W	112 E	112 I
2014	0/0	1/0	1/0	2/0	2/0	2/0
2015	6/3	7/2	10/9	1/0	3/0	3/1
2016	4/0	9/2	21/6	8/2	7/2	6/3
2017	1/0	7/0	49/10	8/3	9/2	8/3
2018	0	4	20	2	3	6

Joinder, Disclaimer, Settlement

- Joinder is a rare event (requested once, and denied)
- Disclaimer occurs (all claims in 3 cases, select claims in others); Board generally denies institution if disclaimed early enough
- Settlements − generally via Joint Motion to Terminate and generally granted

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Common Threads

- More prose-based arguments rather than claim charts
- Liberal use of annotations in graphics
- Highly-sophisticated citation to prior Board decisions
- Most patent owners file Preliminary Responses and most are supported with expert testimony
- Claim construction/eligibility a greater focus

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Aqua Products and Motions to Amend

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Motion to Amend Statistics

Reasons Provided for Denying Entry of Substitute Claims*

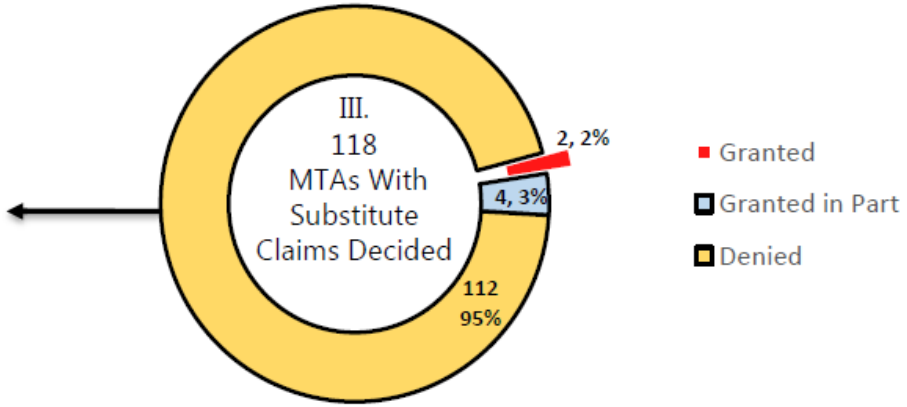
	Reason Given	*# of Cases*	*Pct*
Reasons Based in Whole or Part on 35 U.S.C.:			
101	Non-Statutory Subject Matter	7	6%
112(a)	Written Description	9	8%
112(b)	Definiteness	1	1%
102/103	Anticipated/Obvious Over Art of Record	41	35%
316(d)(3)	Claims Enlarge Scope of Patent	6	5%
316(d)(1)(B)	Unreasonable # Substitute Claims	3	3%
	Multiple Statutory Reasons Given**	27	23%
Reasons Based Solely on Procedure:			
	Cases Where Only Procedural Reasons Given	22	19%
	Totals:	*116*	*100%*

* 116 MTAs requesting entry of substitute claims have been denied in whole or in part.

** Of the "Multiple Statutory Reasons Given" trials, 24 of the 27 trials included "Anticipated/Obvious" as a reason.

Data current as of: 4/30/2016

How Many Motions to Amend Substituting Claims Are Granted?



2, 2%	Granted
4, 3%	Granted in Part
112, 95%	Denied

USPTO MTA Study at 4.

Aqua Products – factual background

- Patent Owner Aqua Products filed a motion to amend in IPR
  - Board determined that Aqua Products did not demonstrate patentability of the amended claims
    - Board issued Final Written Decision (FWD) denying motion to amend
- Aqua Products appealed FWD to the Federal Circuit
  - Federal Circuit panel unanimously affirmed FWD
    - Panel: Reyna, Prost, Stark (by designation)
- Aqua Products sought rehearing en banc

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Aqua Products - result

The only legal conclusions that support and define the judgment of the court are: (1) the PTO has not adopted a rule placing the burden of persuasion with respect to the patentability of amended claims on the patent owner that is entitled to deference; and (2) in the absence of anything that might be entitled deference, the PTO may not place that burden on the patentee. All the rest of our cogitations, whatever label we have placed on them, are just that—cogitations. Even our discussions on whether the statute is ambiguous are mere academic exercises.

The final written decision of the Board in this case is vacated insofar as it denied the patent owner's motion to amend. The matter is remanded for the Board to issue a final decision under § 318(a) assessing the patentability of the proposed substitute claims without placing the burden of persuasion on the patent owner. The Board must follow this same practice in all pending IPRs unless and until the Director engages in notice and comment rule-making. At that point, the court will be tasked with determining whether any practice so adopted is valid.

VACATED AND REMANDED

O'Malley opinion at 66.

Aqua Products, Inc. v. Matal, Case No. 15-1177 (Fed. Cir. Oct. 4, 2017) (en banc)

Aqua Products – Next Steps

PTAB has been issuing orders where the petitioners are now permitted a sur-reply as the final brief filed for proceedings with a motion to amend

Petitioner – Practice Tips

- Ask for a Sur-Reply if patent owner filed a motion to amend
- Likely to see more motions to amend (so plan ahead when preparing petition challenging patent)

Patent Owner – Practice Tips

- Consider motion to amend
- Keep in mind that percentage of granted motions to amend may not change significantly

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Sovereign Immunity as Inter Partes Defense

Sovereign Immunity -- 11th amendment

- States are sovereign under the 11th amendment, and therefore immune from lawsuits unless the state waives or Congress abrogates
- Has been extended to state universities and state_university research foundations
- The USPTO found that Sovereign Immunity applies to IPR proceedings

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The Case That Started it All

- *Covidien LP v. Univ. of Florida Research Found., Inc*. (IPR2016-01274, IPR2016-01275, IPR2016-01276)
  - Covidien filed IPR petitions against patents owned by UFRF
  - PTAB found:
    - Sovereign Immunity is available as a defense in IPR
    - UFRF is an “arm of the state” and therefore a sovereign
    - PTAB dismissed IPRs based on UFRF’s sovereign immunity

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Sovereign Immunity at the PTAB

- Three PTAB panels have found that sovereign immunity applies in IPR
  - In one case, the IPR proceeded without the sovereign present against a non-sovereign co-owner
- PTAB has not yet ruled on whether asserting the patent in district court waives sovereign immunity at the PTAB
  - Several pending cases involve this issue
- It is not clear whether a sovereign immunity decision is reviewable on appeal to the Federal Circuit

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Allergan and Restasis®

- Allergan has 6 orange book listed patents for Restasis®, and asserted them against several generic pharmaceutical companies
- The generics filed IPRs against the 6 patents
- To avoid IPR, Allergan transferred ownership of all 6 patents to the Saint Regis Mohawk Tribe
- Allergan paid the Tribe $13.75M, with additional royalties of up to $15M/year possible
- Allergan's press release stated that the transfer was an attempt to avoid IPR by invoking the Tribe's sovereign immunity

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Allergan Open Questions

- Briefing is complete on the Tribe's motion to dismiss the pending IPRs based on sovereign immunity, awaiting the Board's decision
- The Board has not considered Tribal sovereign immunity before
- Senator McCaskill introduced bill to abrogate Tribal sovereign immunity at PTAB

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Constitutionality of PTAB Trials: *Oil States*

Oil States - History

- Patent Owner Oil States lost at PTAB level in IPR
- Oil States appealed to Federal Circuit, arguing that IPRs are unconstitutional
- Federal Circuit affirmed the PTAB holding without issuing a decision (Rule 36 affirmance)
- Oil States appealed to the Supreme Court
- Supreme Court agreed to hear the case

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Oil States at the Supreme Court

- ***Issue***: Whether *inter partes* review, an adversarial process used by the Patent and Trademark Office (PTO) to analyze the validity of existing patents, violates the Constitution by extinguishing private property rights through a non-Article III forum without a jury.
- What's at stake: the future of all IPRs/PGRs/CBMs
- Over 40 Amicus Briefs filed
- Parties' briefing is complete
- Oral Argument scheduled for November 27, 2017

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Oil States – Are Patents Public or Private Rights?

- ***Article III –*** Only an Article III Court can decide a suit at common law or in equity. *Stern*, 564 U.S. 462, 484 (2011).
  - Suits deciding **public rights** are an exception. *Id.* at 485.
- **Are patents private rights?**
  - *McCormick Harvesting*, 169 U.S. 606, 609 (1898) – "[T]he courts of the United States" are "[t]he only authority competent to set a patent aside, or to annul it, or to correct it for any reason whatever." *See also, Am. Bell Tel. Co.*, 128 U.S. 315, 370 (1888).
- **Are patents public rights?**
  - *Gayler*, 51 U.S. (10 How.) 477, 494 (1851) – "The [patent] monopoly did not exist at common law, and the rights, therefore, which may be exercised under it cannot be regulated by the rules of the common law." *See also, Murray's Lessee*, 59 U.S. (18 How.) 272, 284 (1856); *MCM Portfolio*, 812 F.3d 1284, 1293 (Fed. Cir. 2015).

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Oil States – Going Forward

- Decision expected in first half of 2018
- Petitioner - Practice Tips
  - Weigh waiting to file petition vs. delay
    - 1-year statutory bar
    - Stay of litigation
    - Clearance on product development
- Patent Owner – Practice Tips
  - Maintain pendency of case
    - Request rehearing
    - Appeal to Federal Circuit

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Key Discussion Points:

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► *The speakers will summarize the key takeaways of their presentations.*

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