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Written Description Issues

Nicolas E. Seckel

Intellectual Property Law

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Written description and sections 112, 101

- Stanford v Chinese Uni. Of Hong Kong (CUHK) (Fed. Cir. 2017)
- Visual Memory v. NVIDIA (Fed. Cir. 2017)

Sections 112 and 101

- 35 U.S.C. 112(a): The specification shall contain a **written description of the invention**, and of the manner and process of making and using it...
 - 35 U.S.C. 101: Whoever **invents or discovers any new and useful process, machine, manufacture, or composition of matter**, or any new and useful improvement thereof, may obtain a patent therefor, subject to the **conditions and requirements of this title**
-

Written description and sections 112, 101

- **Stanford v Chinese Uni. Of Hong Kong (CUHK) (Fed. Cir. 2017)**
 - Visual Memory v. NVIDIA (Fed. Cir. 2017)
-

Stanford v CUHK (Fed. Cir. 2017)

- Interference between Quake application (Stanford) and Lo application (CUHK)
 - Claimed invention in dispute is a method to detect fetal DNA in a pregnant woman's blood
 - Uses “massively parallel DNA sequencing”
-

1. A method for determining presence or absence of fetal aneuploidy in a maternal tissue sample comprising fetal and maternal genomic DNA, wherein the method comprises:

- a. obtaining a mixture of fetal and maternal genomic DNA from said maternal tissue sample;
- b. conducting massively parallel DNA sequencing of DNA fragments *randomly selected* from the mixture of fetal and maternal genomic DNA of step a) to determine the sequence of said DNA fragments;
- c. identifying chromosomes to which the sequences obtained in step b) belong;
- d. using the data of step c) to compare an amount of at least one first chromosome in said mixture of maternal and fetal genomic DNA to an amount of at least one second chromosome in said mixture of maternal and fetal genomic DNA, wherein said at least one first chromosome is presumed to be euploid in the fetus, wherein said at least one second chromosome is suspected to be aneuploid in the fetus, thereby determining the presence or absence of said fetal aneuploidy.



A parte:
Ariosa v. Sequenom (Fed Cir. 2015)

- Claim invalidated under section 101 (natural phenomenon without significantly more):
 1. A method for detecting a paternally inherited nucleic acid of fetal origin performed on a maternal serum or plasma sample from a pregnant female, which method comprises
 - amplifying a paternally inherited nucleic acid from the serum or plasma sample and
 - detecting the presence of a paternally inherited nucleic acid of fetal origin in the sample.

Stanford v CUHK (Fed. Cir. 2017):
Quake application prosecution history

- Quake application original claims recited detection of “different target sequences”
- Quake amended the claims to add “conducting massively parallel DNA sequencing of DNA fragments **randomly selected** from the mixture”
- Support in description: “These templates are sequenced using... **products offered by Illumina, Inc., San Diego, Calif.**”

Stanford v CUHK (Fed. Cir. 2017): Issues

- Question in the interference: is “random selection” supported in the Quake description under section 112?
 - PTAB decision: insufficient support
 - Question on appeal: did the PTAB have “substantial evidence” to determine insufficient support
-

Stanford v CUHK (Fed. Cir. 2017): PTAB decision

- PTAB decision relied on CUHK’s expert:
 - Illumina products could do both random and targeted sequencing, so the sentence does not describe random sequencing
-

Stanford v CUHK (Fed. Cir. 2017): Fed. Cir. decision

- Fed. Cir. looked into CUHK expert's sources:
 - Later versions of the Illumina products
 - Post-invention date publications
 - A competing system "Roche 454"
 - No explanation of the correlation with the Illumina products at the time of filing the Quake application
 - Stanford's evidence? Not discussed
 - Reversed and remanded
-

Stanford v CUHK (Fed. Cir. 2017): Conclusion

- Importance of writing a thorough description in the patent application
 - Benefit of building an evidentiary record in PTAB proceedings
 - Expert statements must be supported by factual evidence
-

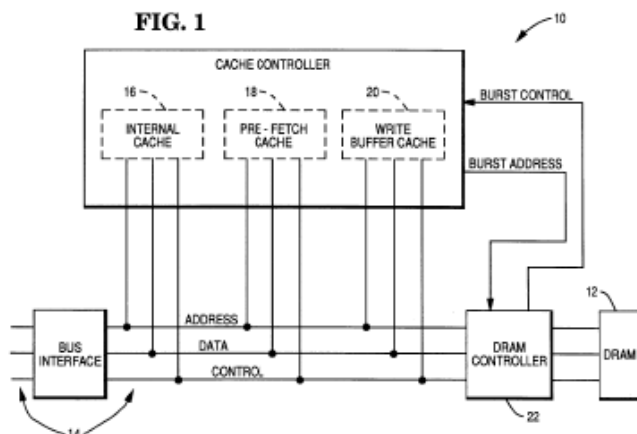
Written description and sections 112, 101

- Stanford v Chinese Uni. Of Hong Kong (CUHK) (Fed. Cir. 2017)
 - **Visual Memory v. NVIDIA (Fed. Cir. 2017)**
-

Visual Memory v. NVIDIA (Fed. Cir. 2017)

- Visual Memory has a patent on a memory system
 - Cache can be programmed differently depending on the type of processor
-

Visual Memory v. NVIDIA (Fed. Cir. 2017)



Visual Memory v. NVIDIA (Fed. Cir. 2017)

1. A computer memory system connectable to a processor and having one or more programmable operational characteristics, said characteristics being defined through configuration by said computer based on the type of said processor, wherein said system is connectable to said processor by a bus, said system comprising:

- a main memory connected to said bus; and
- a cache connected to said bus;

wherein a programmable operational characteristic of said system determines a type of data stored by said cache.



Visual Memory v. NVIDIA (Fed. Cir. 2017)

- District Court under FRCP rule 12(b)(6) (motion to dismiss): abstract idea without significantly more
 - Federal Circuit: reversed and remanded as not directed to an abstract idea (Alice step 1)
 - Abstract idea: categorical data storage
 - Claimed invention: interoperable computer memory
-

Visual Memory v. NVIDIA (Fed. Cir. 2017)

- Evidence: Fed. Cir. cites two specific portions from the patent specification:
 - Microfiche appendix having a combined total of 263 frames of computer code
 - “[f]or a system employing a 386 or 386sx system processor, internal cache 16 holds only code data, whereas for a system employing a 486 processor, internal cache 16 holds both code and non-code data.”
-

Visual Memory v. NVIDIA (Fed. Cir. 2017)

- Dissent:
 - Alice step 1: claimed programmable operational characteristic is a “black box”, i.e., an abstract idea
 - Alice step 2: code appendix to the specification may contain an “inventive concept” but it is not recited in the claim
-

Visual Memory v. NVIDIA (Fed. Cir. 2017): Conclusion

- Surviving judicial exceptions analysis:
importance of writing a thorough and detailed description in the patent application
-

Questions, comments?

Nicolas E. Seckel
(1) 202-822-1100
nseckel@whda.com

This presentation is not legal advice

www.WHDApatentlaw.com



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KSR 10 Years Later: Obviousness Update

Nicolas E. Seckel

Intellectual Property Law

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Introduction: Graham v. Deere (Supreme Court 1966)

- Obviousness is a question of law based on underlying questions of facts:
 - Scope and content of the prior art
 - Differences between the claimed invention and the prior art
 - Level of ordinary skill in the pertinent art
 - Ultimate legal conclusion as to obviousness
 - See USPTO Guidelines (MPEP 2141)
-

Introduction: KSR v. Teleflex (Supreme Court 2007)

- KSR rationales for combining or modifying prior art:
 - A. Combining prior art elements according to known methods to yield predictable results;
 - B. Simple substitution of one known element for another to obtain predictable results;
 - C. Use of known technique to improve similar devices (methods or products) in the same way;
 - D. Applying a known technique to a known device (method or product) ready for improvement to yield predictable results;
 - E. “Obvious to try”—choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success;
 - F. Known work in one field of endeavor may prompt variations of it for use in either the same field or a different one based on design incentives or other market forces if the variations would have been predictable to one of ordinary skill in the art; and
 - G. Some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention.
 - See MPEP 2143
-

Obviousness examination at the USPTO

- Concept of “prima facie” obviousness
 - USPTO (Examiner, or PTAB on appeal) must explain the rationale in rejections of claims
 - See MPEP 2142
 - Rebuttal by applicant
 - Arguments traversing “prima facie” obviousness (the USPTO misinterpreted the prior art)
 - Evidence rebutting “prima facie” obviousness (the USPTO did not consider all the evidence)
 - The USPTO reviews the totality of the evidence
 - See MPEP 2145
-

Obviousness in PGP, litigation

- No “prima facie” concept
 - Burden of proof is always on the patent challenger
 - All the evidence is considered at the same time
 - Prior art of record
 - “Secondary considerations” or “objective indicia” of non-obviousness (unexpected results, commercial success, long-felt need, recognition from public, copying, etc.)
-

Obviousness cases: secondary considerations of non-obviousness

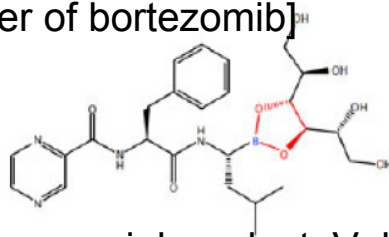
- Novartis v. Watson (Fed. Cir. 2017)
 - WBC v. Crown Packaging (PTAB 2017)
-

Obviousness cases: secondary considerations of non-obviousness

- **Novartis v. Watson (Fed. Cir. 2017)**
 - WBC v. Crown Packaging (PTAB 2017)
-

Millenium v. Sandoz (Fed. Cir. 2017)

- Millenium has a patent on a formulation for bortezomib (anti-cancer drug)
- Patent claim: The lyophilized compound D-mannitol- [ester of bortezomib]



- Successful commercial product: Velcade®
-

Millenium v. Sandoz (Fed. Cir. 2017)

- Millenium sued Sandoz in District Court for patent infringement
 - District Court: invalid for obviousness
 - Strong suggestion in prior art:
 - Lyophilization is well-known drug preparation technique
 - Mannitol is well-known excipient
 - Secondary consideration insufficient:
 - Unexpected results not linked to closest prior art
 - Commercial success not linked to chemical structure
-

Millenium v. Sandoz (Fed. Cir. 2017)

- Sandoz expert:
 - Mannitol is commonly used for lyophilization
 - Stable ester formation with mannitol is inherent result of lyophilization
 - Dissolution of ester in bloodstream was expected
 - Millenium expert:
 - Person of the art would have tried to avoid forming an ester of bortezomib
 - Mannitol ester of bortezomib had improved stability and solubility
-

Millenium v. Sandoz (Fed. Cir. 2017)

- Federal Circuit: no “inherency” concept in obviousness
 - Prior art taught that bortezomib is unstable
 - No expert testified that stability and preservation of therapeutic effect by lyophilization with mannitol was expected
-

Millenium v. Sandoz (Fed. Cir. 2017): Secondary considerations

- Unexpected results:
 - Prior art only taught improved stability for glycerol esters, not mannitol esters, without prediction as to therapeutic effect
 - Expert did not have to compare with glycerol esters of bortezomib
 - Long-felt need:
 - Bortezomib alone was denied FDA approval
 - Commercial success is due to the mannitol ester
-

Millenium v. Sandoz (Fed. Cir. 2017): Conclusion

- Comparative results and argument about actual prior art (bortezomib alone), not glycerol ester of bortezomib
 - District Court was found to have made a “clear error” in weighing the expert evidence
 - Secondary considerations made a difference
 - FDA previous rejection of bortezomib drug proved the correlation (“nexus”)
-

Obviousness cases: secondary considerations of non-obviousness

- Novartis v. Watson (Fed. Cir. 2017)
 - **WBC v. Crown Packaging (PTAB 2017)**
-

WBC v. Crown Packaging (PTAB 2017)

- Crown Packaging has a patent on a bottle cap
 - Grooved crown
 - Harder, thinner steel
 - WBC petitioned for inter partes review (IPR) based on two prior art documents:
 - “Wagner”: bottle cap with grooved crown and crimped skirt
 - “Industrial”: harder steel
-

Crown Packaging patent

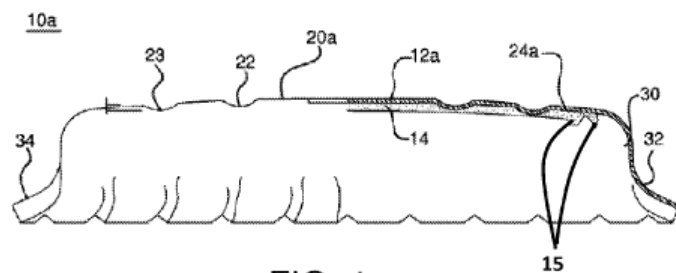
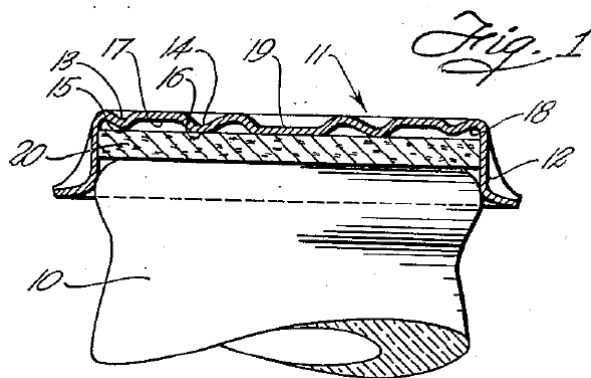


FIG. 1

Wagner prior art

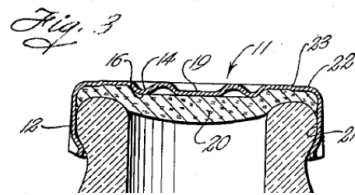


WBC v. Crown Packaging (PTAB 2017): Petitioner's evidence

- WBC documents and expert: industry trend to use thinner but harder caps
-

WBC v. Crown Packaging (PTAB 2017): Patent owner's evidence

- CP expert: harder steel would interfere with stretching to form the skirt
 - Commercial success
 - Industry praise
 - Copying
-



WBC v. Crown Packaging (PTAB 2017): Secondary considerations

- Commercial success in Peru:
 - Market share of Crown Packaging went from 88% to 95% after introduction of harder crown cap
 - Environmental award in Peru
 - Praise in international industry publications
 - Inventor testimony: difficult to crimp crown cap in spite of harder steel
 - WBC copied the invention
-

WBC v. Crown Packaging (PTAB 2017)

- Convincing:
 - Commercial success in Peru :
 - no evidence by petitioner that quasi-monopoly in Peru is not representative of an open market
 - Industry praise, environmental award:
 - expert testimony about long availability of harder steels established the correlation (“nexus”)
-

WBC v. Crown Packaging (PTAB 2017)

- Not convincing:
 - Inventor testimony: redundant with expert
 - Copying: patent application was copied, but no evidence of actual comparative testing
-

WBC v. Crown Packaging (PTAB 2017): Conclusion

- In this case, the unexpected result evidence was not conclusive
 - Extensive record on secondary considerations made the difference
 - Petitioner did not rebut effectively (only argument, not evidence)
-

Conclusion

- Benefits of building a thorough and creative evidentiary record in prosecution, reviews, and litigation
-

Questions, comments?

Nicolas E. Seckel
(1) 202-822-1100
nseckel@whda.com

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Experimental use exception to infringement

- General experimental use: very limited
 - Common law
 - *Madey v. Duke Uni.* (Fed. Cir. 2002)
 - Administrative authorization experimental use: complex
 - 35 U.S.C. 271(e) (1988)
 - *Roche v. Bolar* (Fed. Cir. 1984)
 - Research tools: complex and unsettled
 - *Proveris v. Innova* (Fed. Cir. 2008)
-

Common law experimental use: Madey v. Duke Uni. (Fed. Cir. 2002)

- Madey had a patent on a laser
 - Duke University used patented laser in a lab to teach students
 - Madey sued for patent infringement
 - District Court: use is experimental in nature
 - Common law (judicially-created) exception to infringement
-

Common law experimental use: Madey v. Duke Uni. (Fed. Cir. 2002)

- Federal Circuit: common law experimental use exception covers scientific inquiry, not business purposes
 - Teaching students is the university's business, even if non-profit
-

Administrative experimental use: Roche v. Bolar (Fed. Cir. 1984)

- Roche had patent on a drug
 - Bolar made and used the drug to generate data for submission to FDA to obtain administrative authorization
 - Roche sued for infringement
 - District Court: covered by common law exception to infringement
-

Administrative experimental use: Roche v. Bolar (Fed. Cir. 1984)

- Federal Circuit: scientific inquiry does not extend to substantial commercial purpose
-

Legislative experimental use: “Safe harbor” of 35 U.S.C. 271(e)

- 35 U.S.C. 271(e) (1986-1988): legislative overruling of Roche v. Bolar for some drugs and medical devices
 - “Safe harbor” protection from infringement when activities are “solely for uses reasonably related to the development and submission of information” to administrative agency (FDA or USDA)
-

“Safe harbor” and “research tools”

- No “safe harbor” for sale of laboratory tools not subject to the FDA procedure
 - Proveris v. Innova (Fed. Cir. 2008): aerosol testing system used to generate data on medical device for FDA application
 - “Safe harbor” may apply to use of substances in testing even if not subject to the FDA procedure
 - Integra v. Merck (S. Ct. 2005): peptides used as controls in tests to select drug for FDA application
-

Conclusion

 **It's Complicated**

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Nicolas E. Seckel
(1) 202-822-1100
nseckel@whda.com

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Client-Attorney Privilege: Updates and Practices

Nicolas E. Seckel

Intellectual Property Law

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Introduction:

U.S. judicial system is adversarial

- Parties exchange factual evidence (not directed by the judge)
 - “Discovery” phase of litigation: proportional to the needs of the case
- Parties choose and present witnesses and experts (not directed by the judge)
 - Cross-examination of witnesses
- Judge is an umpire (arbiter)
 - Review on appeal for abuse of discretion

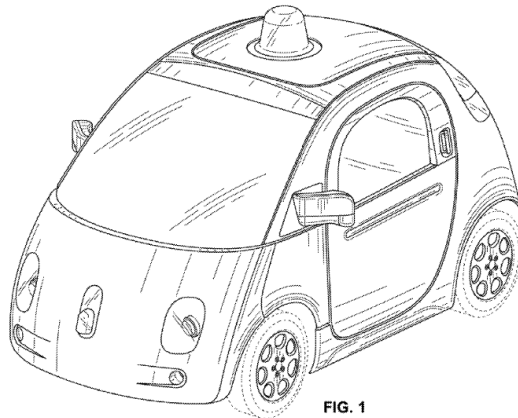
Introduction: Exceptions to discovery

- Client-attorney privilege
 - Communications between a client and their attorney
 - For the purpose of requesting legal advice
 - If not waived
 - Attorney work-product privilege
 - Information prepared by a client or its lawyer
 - In anticipation of litigation
-

Introduction: Exceptions to discovery

- Other exceptions to discovery:
 - Other privileges (spousal, medical...)
 - Trial preparation
 - Communications with experts...
-

Waymo v. Uber (N. D. Cal July 6, 2017)



Source: US Pat. D734,211

Waymo v. Uber (N. D. Cal July 6, 2017)

- Levandowski was engineer in charge of autonomous driving program at Waymo
- Levandowski quit Waymo, formed his own company Otto
- Uber bought Otto, hired Levandowski
- Waymo sued Uber for misappropriation of trade secrets
 - Accuses Levandowski of giving Waymo documents to Uber on autonomous driving
- Uber fired Levandowski

Privilege issue: due diligence report

- Before Uber decided to acquire Otto, Uber and Otto hired a law firm to prepare a due diligence report
 - The law firm interviewed Levandowski
-

District Court on due diligence report: client-attorney privileged?

- Uber: no client-attorney privilege because no common interest with Otto, the investigating law firm was only a common agent
 - Otto: no client-attorney privilege because Levandowski was not interviewed as official of Otto, but in individual capacity
 - Levandowski: no client-attorney privilege because he was not a client of the law firm
-

District Court on due diligence report: attorney work-product privilege?

- No work-product privilege
 - Before acquisition decision, Uber, Otto and Levandowski had adverse legal interests
 - No evidence of a common legal strategy when the investigating law firm was hired by Uber and Otto
 - Any work-product privilege was waived
 - Even if Uber had a work-product privilege, it would have been waived by sharing the report with Otto and Levandowski
-

District Court on due diligence report: “common interest” protection?

- Common interest doctrine does not create a separate privilege
 - Avoids waiver of an existing privilege if:
 - There is a common interest
 - Information or documents are exchanged to further the common interest
 - No waiver
-

Uber and Otto: no common interest

- Before acquisition decision, legal interests were not aligned
 - Investigation was not for the purpose of any common legal interest
 - Later-signed “joint defense agreement” was signed after the acquisition decision
-

Uber and Levandowki: no common interest

- Uber-Otto acquisition agreement includes indemnification of employees for claims by former employers (Waymo)
 - Indemnification includes misappropriation of trade secrets
 - But: the protection does not apply to acts before the acquisition agreement was signed
-

To be continued...

- On appeal at the Federal Circuit
 - District Court order stayed
 - Expedited briefing
 - Decision expected soon
-

Conclusion

- Trade secrets are an important legal field
 - Now Federal law
 - Client-attorney privilege is a fact-intensive legal field
 - Legal strategy considerations conflict with business needs
 - Common interest, joint defense agreements can be useful
 - If they correlate to the reality
-

Questions, comments?

Nicolas E. Seckel
(1) 202-822-1100
nseckel@whda.com

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www.WHDApatentlaw.com



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Update on Post-Grant Proceedings

Nicolas E. Seckel

Intellectual Property Law

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Introduction: Post-Grant Proceedings (PGP)

- Inter Partes Review (IPR)
 - All enforceable patents, at any time
 - Anticipation/obviousness, patents and publications
 - Post-Grant Review (PGR)
 - First-to-file patents only, within 9 months from issuance
 - Anticipation, obviousness, indefiniteness, sufficiency of description (except best mode), patent-eligibility
 - Covered Business Method Patent Review (CBM)
 - Non-technological financial services patents
 - Derivation Proceeding (DER)
 - Interference phased out March 16, 2013
-

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Introduction: PGPs are different from EPO oppositions

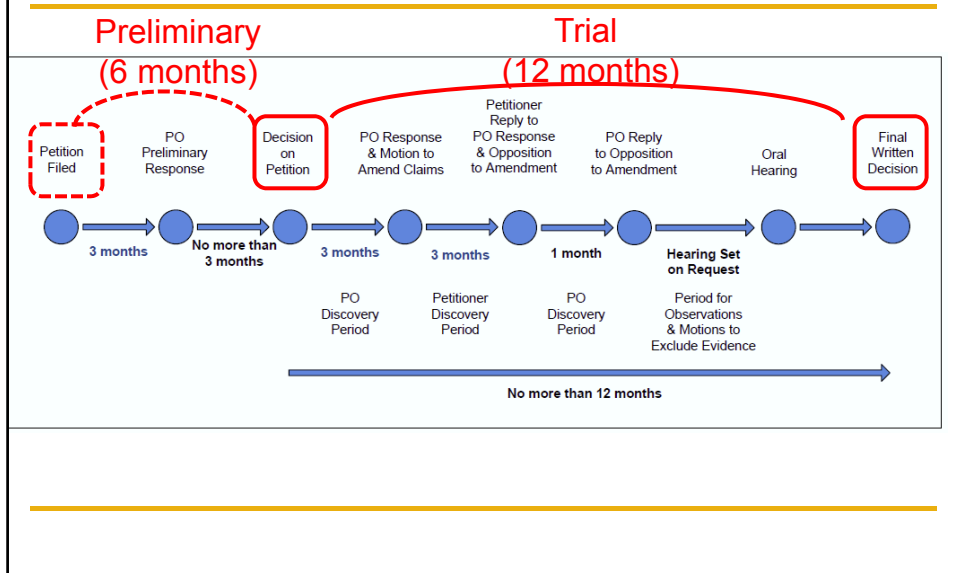
Petitioner:

1. No anonymity
2. No automatic institution
3. Estoppel attaches to final decision

Patent owner:

4. Broad claim interpretation
 5. Limited right to amend
 6. Patent Owner estoppel
-

Introduction: PGP timeline



Update on Post-Grant Proceedings

- In re Aqua Products: patent owner's right to amend
- SAS v. Matal: partial institution of PGP
- Oil States v. Greene: constitutionality of PGP

Update on Post-Grant Proceedings

- **In re Aqua Products: patent owner's right to amend**
 - SAS v. Matal: partial institution of PGP
 - Oil States v. Greene: constitutionality of PGP
-

Patent Owner right to amend

- 35 U.S.C. 316(d): patent owner may file one motion to amend
 - 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.
-

Patent owner's burden of proof

- PTAB: Patent owner has the burden of proof in a motion to amend
 - Patentable distinction over the prior art of record
 - Patentable distinction over other proposed claims
 - Idle Free v. Bergstrom (PTAB 2013); Nike v. Adidas (Fed. Cir. Feb 11, 2016)
-

Contradiction between AIA statute and USPTO regulation?

- 35 U.S.C. 316(e): “In an inter partes review instituted under this chapter, the **petitioner shall have the burden of proving a proposition of unpatentability** by a preponderance of the evidence.”
 - 37 C.F.R. 42.20: “The **moving party has the burden of proof** to establish that it is entitled to the requested relief.”
-

Burden of proof

- Burden of production: coming forward with presentation of evidence
 - Proposed amended claims meet statutes and regulations (written description, not broader than original claims, etc.)
 - Evidence/argument of patentability over the art
 - Burden of persuasion: convince the trier of facts
 - In IPR: patentability over the art must be “more likely than not” (preponderance of the evidence)
-

In re Aqua Products (Federal Circuit): Timeline

- Aug 22, 2014: PTAB final written decision cancelling all patent claims
 - Patent owner’s motion to amend was denied
 - May 25, 2016: affirmed by a Federal panel
 - Burden of proof allocation to patent owner is dictated by precedent
 - Aug. 12, 2016: vacated for review “en banc”
-

In re Aqua Products (Federal Circuit): “en banc” decision

- October 4, 2017 “en banc” decision: reversed and remanded
 - **Petitioner has the burden of persuasion** (6 of 11 judges)
 - Patent owner has a burden of production, but no agreement on its scope (6 of 11 judges)
-

In re Aqua Products (Federal Circuit): no majority

- Patent procedure: what is the burden of production allocation?
 - For granting a motion to amend?
 - For entering proposed claims in IPR record?
 - For deciding patentability of proposed claims?
 - Administrative procedure: how can the USPTO decide the burden of proof allocation?
 - Only public-notice regulations?
 - PTAB precedential decisions?
 - Informal guidance?
-

In re Aqua Products (Federal Circuit): conclusion

- Supreme Court review?
-

Update on Post-Grant Proceedings

- In re Aqua Products: patent owner's right to amend
 - **SAS v. Matal: partial institution of PGP**
 - Oil States v. Greene: constitutionality of PGP
-

SAS v. Matal

- Current USPTO practice: claim-by-claim, ground-by-ground institution
 - Drawback: grounds not instituted
 - Do not meet burden of proof for institution
 - PGR: “more likely than not” that challenged claim unpatentable
 - IPR: “reasonable likelihood”
 - Advantage: protection from estoppel
-

SAS v. Matal

Question on review by Supreme Court

- Whether 35 U.S.C. § 318(a) ... requires [the] Board to **issue a final written decision as to every claim challenged by the petitioner**, or whether it allows that Board to issue a final written decision with respect to the patentability of only some of the patent claims challenged by the petitioner, as the U.S. Court of Appeals for the Federal Circuit held.
-

Consequences for petitioners

- More effective procedure, or more clutter during IPR trial?
 - Broader estoppel effect without the safe harbor of “challenged/not instituted” grounds?
 - 35 U.S.C. 315(e): “any ground that the petitioner **raised or reasonably could have raised** during that inter partes review”
-

Update on Post-Grant Proceedings

- In re Aqua Products: patent owner’s right to amend
 - SAS v. Matal: partial institution of PGP
 - **Oil States v. Greene: constitutionality of PGP**
-

Oil States v. Greene

- 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.
-

Conclusion

- Aqua Products is part of the “re-balancing” of the IPR-PGR procedures in favor of Patent Owners
 - SAS and Oil States are more basic challenges to these procedures
 - Elimination of claim-by-claim, ground-by-ground institution of PGP would favor petitioners
 - Elimination of all PGP would favor patent owners
-

Bonus case on constitutional challenges: Sovereign immunity of Indian tribes



THE WALL STREET JOURNAL.



BUSINESS

Allergan Partners With Indian Tribe to Protect Drug Patents

Move meant to insulate Restasis from challenges at the U.S.
Patent and Trademark Office

By Jonathan D. Rockoff

Updated Sept. 8, 2017 4:29 p.m. ET

Questions, comments?

Nicolas E. Seckel
(1) 202-822-1100
nseckel@whda.com

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