THE PRACTICAL IP FOR NATURAL SCIENCES WEBINAR SERIES

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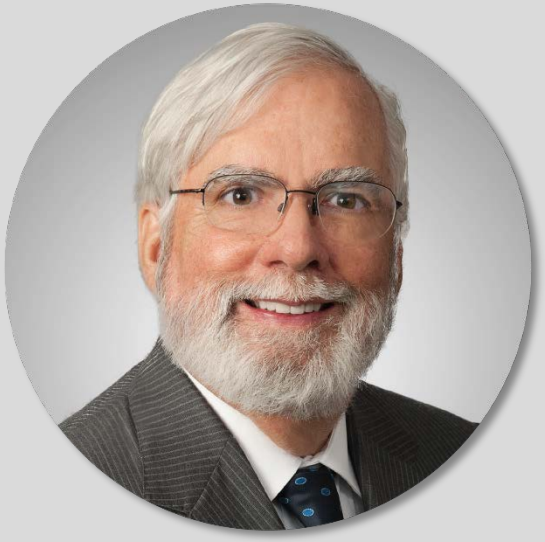
THE PRACTICAL IP FOR NATURAL SCIENCES WEBINAR SERIES

TOP 5 COURT DECISIONS
IMPACTING FUTURE IP LITIGATION

THURSDAY, MAY 17, 2018 @ 1:00PM (CT)

MEET THE PRESENTER



Warren Woessner - *B.A., Ph.D., J.D*

- Patent Attorney & Founding Shareholder
- Focus on Chemical Patent Law
- Expert Witness on Complex Prosecution Problems

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It's been a busy year. Top 5 from 2017-2018

1. Oil States Energy Services v. Greene's Energy Group, Appeal no. 16-712 (April 24, 2018).
2. SAS Institute Inc. v. Iancu, Appeal No. 16-969 (April 24, 2018).
3. Bosch Automotive Service Solutions, LLC v. Matal (Intervenor), Appeal no. 2015-1928 (Fed. Cir., December 22, 2017)
4. Cleveland Clinic Foundation v. True Health Diagnostics LLC, Petition for a Writ of Certiorari, No. 17-__ (January 16, 2008); from Appeal No. 2016-1766 (Fed. Cir., June 16, 2017).
5. Vanda Pharm., Inc. v. West-Ward Pharm. Int'l Ltd, Appeal No. 2106-2707, -08 (Fed. Cir. Aril 18, 2018).

Inter Partes Review (IPR) Survives Constitutional Challenge – Does not Violate Art. III or 7th Am't.

- In Oil States, a divided S. Ct. held 7/2 that the grant of a patent falls within the public rights doctrine, as a matter "arising between the government and others" [like a fishing license] and not a private right (like ownership of land].
- Held: IPR is an appropriate exercise of Congress to assign adjudication of public rights to the PTO, and Congress is not required to assign such adjudications to Article III courts for resolution by a jury trial (Also eliminates 7th Amendment arguments).
- Dissent argued that decision endorsed an unfair weakening of patent protection against the threat of gov't intrusion and dispossession.

SAS: IPR Requires PTO to Decide Patentability of All the Claims Challenged by Petitioner.

- Divided S. Ct. (5/4) rejected a PTO regulation that recognized a power of "partial institution" of IPR involving review of fewer than all of the claims. No Chevron deference to agency acting beyond stat. auth.
- Majority read 35 USC 318(a) to require final written decision to address the patentability of all of the original, remaining or substitute claims "at the end of the litigation."
- PTO has proposed that "broadest reasonable interpretation" standard of claim construction as applied in post-grant proceedings such as IPR be replaced with Phillips standard used by the courts.
- The two changes should help streamline upcoming litigation when the claims surviving IPR return to court (increased deference).

Aqua Products Sinks PTAB Decision in Bosch

- Acting Director Mattal named as a party, representing the Board, after original defendant-winner chose not to participate in the appeal.
- Fed. Cir. affirmed Board's ruling that original claims were obvious but vacated denial of Bosch's contingent motion to substitute an amended claim set.
- Fed. Cir. rejected the Board's ruling that "the patent owner bears the burden of proof in demonstrating patentability of the proposed substitute claims over the prior art in general, and thus, entitlement to add these claims to its patent."
- Suggestion that failure of PTAB or challenger to meet this burden entitles patent owner to "amend" to enter the substitute claims.

Cleveland Clinic Fights for Diagnostic Claims

- Meriel/Ariosa, applying the Mayo/Alice rule, established that the discovery of a naturally-occurring correlation between a biomarker and a disease is per se patent ineligible as an attempt to claim a natural phenomenon, unless the claims contain a further "inventive concept" and did not simply recite steps that were routine, well-known and conventional.
- Cleveland Clinic lost its patents claiming a method to diagnose cardiovascular disease by measuring the levels of a biomarker, MPO, in the blood.
- The Fed. Cir. held that the steps required to carry out the test used "known statistical models" and that C.C. "does not purport to derive new statistical methods to arrive at the …levels of MPO that would that would indicate [CVD] risk" and that the spec. called many of the methods conventional. Appeal no. 2016-1766 (June 16, 2017)

Cleveland Clinic Petitions for Writ of Cert.

- The Clinic has decided to do more "purporting" about the detection and comparison steps.
- Questions Presented:

  1) Did the Fed. Cir. err in holding that a ("claim to a") method involving natural phenomena is ineligible if it claims ("recites"?) known techniques that have been adapted for a new use and purpose not previously known in the art?

  2) Does the 7th amendment permit invalidation of patent claims under s. 101 on the pleadings when there are disputed questions of fact, claim construction and/or an undeveloped evidentiary record?

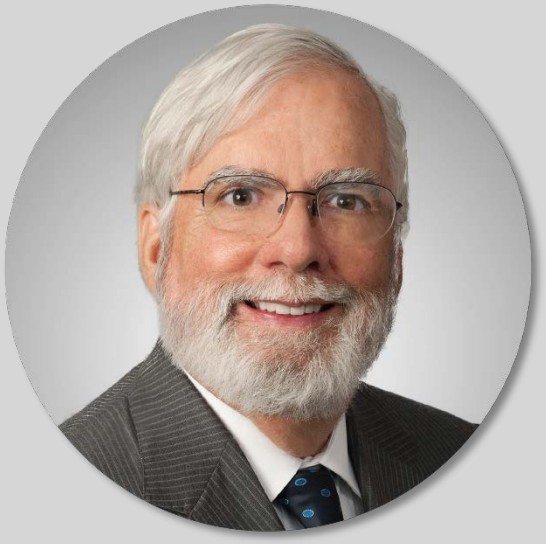
Cleveland Clinic's Case For Cert.

- PRO: The specification has columns of detailed information on measurement techniques and statistical analyses required to make the test reliable. Assigning weight to health factors requires clinical "value judgments" by the hand of man.
- The PTO found that the claims were unobvious, and that the art believed that detection of the marker in blood samples was novel and its correlation to CVD was unreliable.
- Berkheimer v. HP, Inc. recently held that whether or not a claim element represents well-understood, routine, conventional activity raises a disputed factual issue that precludes SJ that claim fails 101.
- PTO has released "revised guidance" requiring Examiners to support finding that claims fails MPEP 2106, Step 2B. Released May 8, 2018.

Fed. Cir. Circumvents Mayo/Alice Rule in Vanda

- Claims were directed to an improved method of treating schizophrenia (“SC”) with ilorperidone (Ilo) comprising genotyping patients to find if they are a poor metabolizer of lio due to low levels of enzyme CYP2D6 ; and dosing them with less than 12 mg/day to avoid QTc prolongation (a heart arrhythmia) while giving 12mg/day-24mg/day to normal metabolizers.
- Divided Fed. Cir. panel held that claims were not an attempt to claim a natural phenomenon, distinguishing Mayo as a diagnostic method, while the Vanda claim was new way of using an existing drug that improves its safety. So no Step 2B (“inventive concept”) inquiry was needed.
- Specificity of compound, dose and outcome was important.

QUESTIONS & DISCUSSION



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RESURGENCE

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THURSDAY, JUNE 14, 2018 @ 1:00PM (CT)