

Case law Update and Changes to the Board

- PIUG (Denver CO, May 1, 2012)
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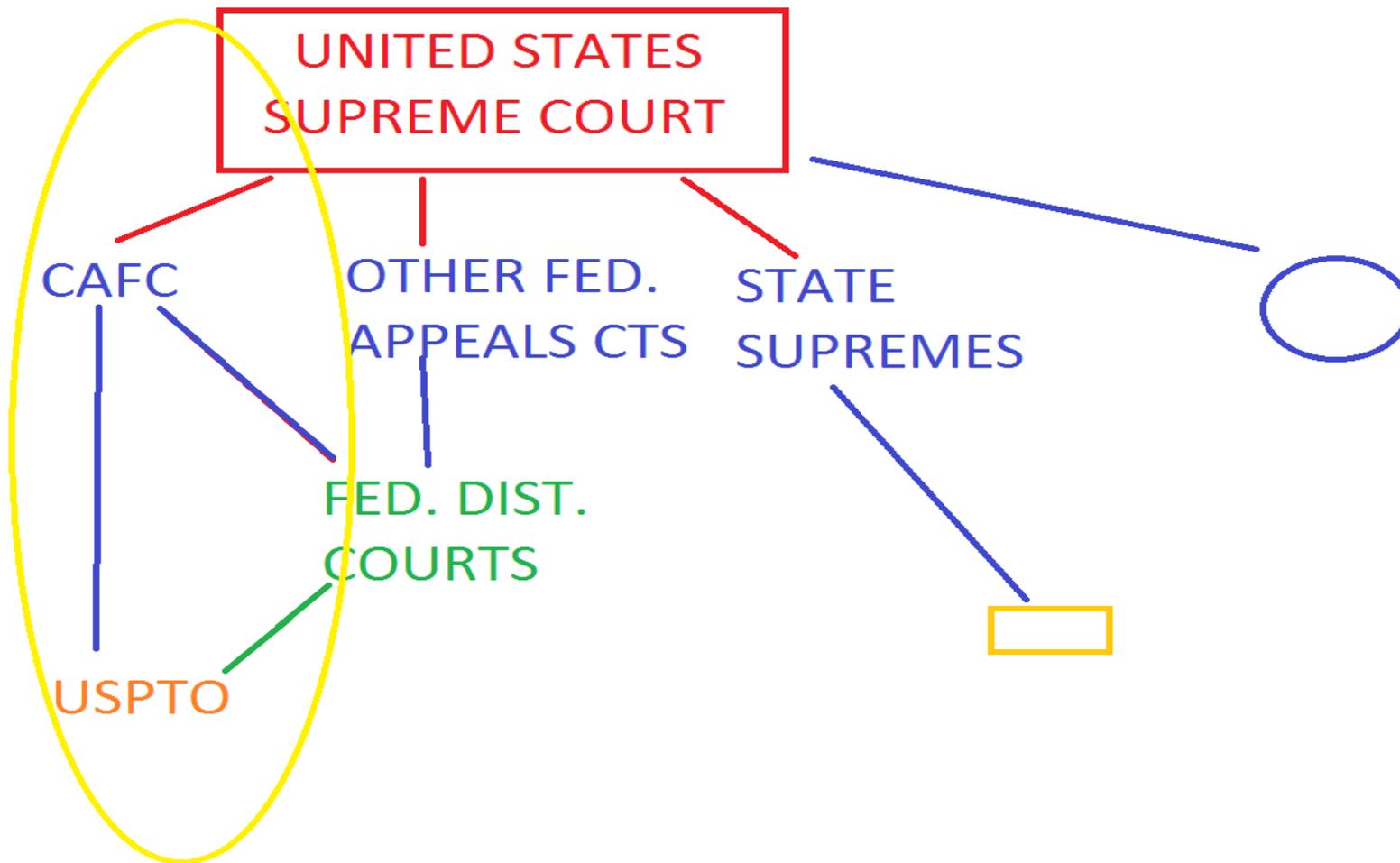
OUTLINE

1. COURTS OUTLINE

2. CASE LAW UPDATE (2010 TO PRESENT)

3. CHANGES TO THE BOARD

COURTS OUTLINE



SUPREME COURT 2011 -2012

- 101 PATENT ELIGIBILITY
- *Mayo v. Prometheus*, decided 3/2012.
- Supreme Court Reversed The CAFC!

MAYO CLAIM AT ISSUE

A method of optimizing therapeutic efficacy for treatment of an immune-mediated gastrointestinal disorder, comprising:

- (a) **administering** a drug providing 6-thioguanine to a subject having said immune-mediated gastrointestinal disorder; and
- (b) **determining** the level of 6-thioguanine in said subject having said immune-mediated gastrointestinal disorder, **wherein** the level of 6-thioguanine less than about 230 pmol per 8×10^8 red blood cells indicates a need to increase the amount of said drug subsequently administered to said subject and **wherein** the level of 6-thioguanine greater than about 400 pmol per 8×10^8 red blood cells indicates a need to decrease the amount of said drug subsequently administered to said subject.

MAYO HISTORY

DISTRICT COURT: Not Patentable Subject Matter

CAFC PREDICATE: Novelty, Obviousness, Overbreadth, Not Relevant To 101 Analysis

CAFC CONCLUSION: “ADMINISTERING” Results In Biological Changes, Transformation. Patentable.

MAYO SUPREME COURT QUESTION

- “whether the claims do significantly more than simply describe these natural relations.”
- “To put the matter more precisely, do the patent claims add enough to their statements of the correlations to allow the processes they describe to qualify as patent-eligible processes that apply natural laws?”

MAYO - SUPREME COURT

- SUPREME COURT ANALYSIS ALGORITHM
- STEP 1 – FIND THAT THE FOLLOWING IS A LAW OF NATURE
- "relationships between concentrations of certain metabolites in the blood and the likelihood that a dosage of a thiopurine drug will prove ineffective or cause harm"

MAYO - SUPREME COURT

- SUPREME COURT ANALYSIS
- STEP 2 – FIND THAT “ADMINISTERING” AND DETERMINING DRUG “LEVEL” ARE “well-understood, routine, conventional activity, previously engaged in by those in the field.”

MAYO - SUPREME COURT

- SUPREME COURT ANALYSIS
- STEP 3 – CONCLUDE THAT APPLYING “well-understood, routine, conventional activity, previously engaged in by those in the field.” TO A LAW OF NATURE IS NOT PATENTABLE SUBJECT MATTER

MAYO SUPREME COURT CONCLUSION

- The claimed invention added "nothing specific to the laws of nature other than what is well-understood, routine, conventional activity, previously engaged in by those in the field."
- The claimed invention defines an unpatentable law of nature

SUPREME COURT 2011 -2012

- MAYO INQUIRIES:
- Method claim?
- Claim a law of nature?
- Claimed activity conventional?*
- Claimed activity previously engaged in?*
- Engaged in by those *in the field?*

SUPREME COURT 2011 -2012

- WHITHER *MYRIAD*?
- (In *Myriad I*, CAFC held claims to “isolated” DNA are patent eligible; method of screening cell growth rates patent eligible; and mere mental step claims patent ineligible.)
- 3/27/12 – SUPREMES REMANDED *MYRIAD* TO CAFC FOR REVIEW IN LIGHT OF *MAYO*.

OTHER SUPREME COURT DECISIONS

- ***MS v. i4i*: 35 USC 282, PRESUMPTION OF VALIDITY (STILL) REQUIRES CLEAR AND CONVINCING PROOF OF INVALIDITY**
- ***Stanford v. Roche*: INVENTORS (STILL) OWN THEIR INVENTIONS. (No automatic divesting of federally funded research, by Bayh-Dole Act)**
- ***Global-tech Appliances, Inc. v. Seb S. A.*: – Inducing infringement requires knowledge that the induced act infringes the patent. But, a showing of “willful blindness” by the inducer is sufficient to meet the knowledge requirement. (“Under this formulation, a willfully blind defendant is one who takes deliberate actions to avoid confirming a high probability of wrongdoing and who can almost be said to have actually known the critical facts.”)**

SUPREME COURT PENDING PATENT CASES

- *Caraco v. Novo Nordisk*, argued, awaiting decision. (CAFC held that DJ jurisdiction extends to counterclaim DJ required for obtaining an exclusivity period. Misdescriptive patentee FDA submission situation.)
- *Kappos v. Hyatt*, argued, awaiting decision. (CAFC, en banc, held that 35 USC 145 imposed no limitations on evidence admissible in a District Court review of PTO denial of a patent).

CAFC, USPTO BOARD, AND DISTRICT COURTS

See “Summary of Selected Patent
Cases from 2011 through
3-22-2012” By Rick Neifeld, March
22, 2012

on our firm’s Publications page:

<http://www.neifeld.com/advidx.html>

CASE LAW UPDATE

- <http://www.neifeld.com/cases.pdf>
- (*FREE* ONLINE CASE LAW BOOK)

CHANGES TO THE BOARD

- PROBLEM – HOW CAN WE PROVIDE FOR TIMELY EFFICIENT CORRECTION OF ARGUABLY DEFECTIVE PATENTS?
- ANSWER – GIVE THE PUBLIC LOTS OF OPTIONS
- IN SHORT, THAT IS WHAT THE AIA DOES

BOARD AND EXAMINING CORP JURISDICTION SPLIT

- AIA - ALL EX PARTE PATENT CORRECTIONS HANDLED BY THE *EXAMINING CORP*
- AIA – ALL INTER PARTES PATENT CORRECTIONS HANDLED BY THE *BOARD*
- BOARD PROCEEDINGS ARE *ADVERSARIAL PROCEEDINGS*

BOARD ADVERSARIAL PROCEEDINGS (TRIALS)

- ALL PARTIES GET TO ARGUE EACH POINT
- NO EX PARTE COMM. WITH THE JUDGES
- FEDERAL RULES OF EVIDENCE APPLY
- WITNESSES ARE SUBJECT TO CROSS-EXAMINATION
- LIMITED DISCOVER EXISTS
- *WRITING* LIMITS

SUNSET PROCEEDINGS

- **INTER PARTES REEXAMINATIONS
(EXAM CORP)**

SUNSET: REQUIRES PETITION FILED PRIOR TO 9/16/2012 (LAST INTER PARTES REEXAMINATION SHOULD BE TERMINATE CIRCA 2022)

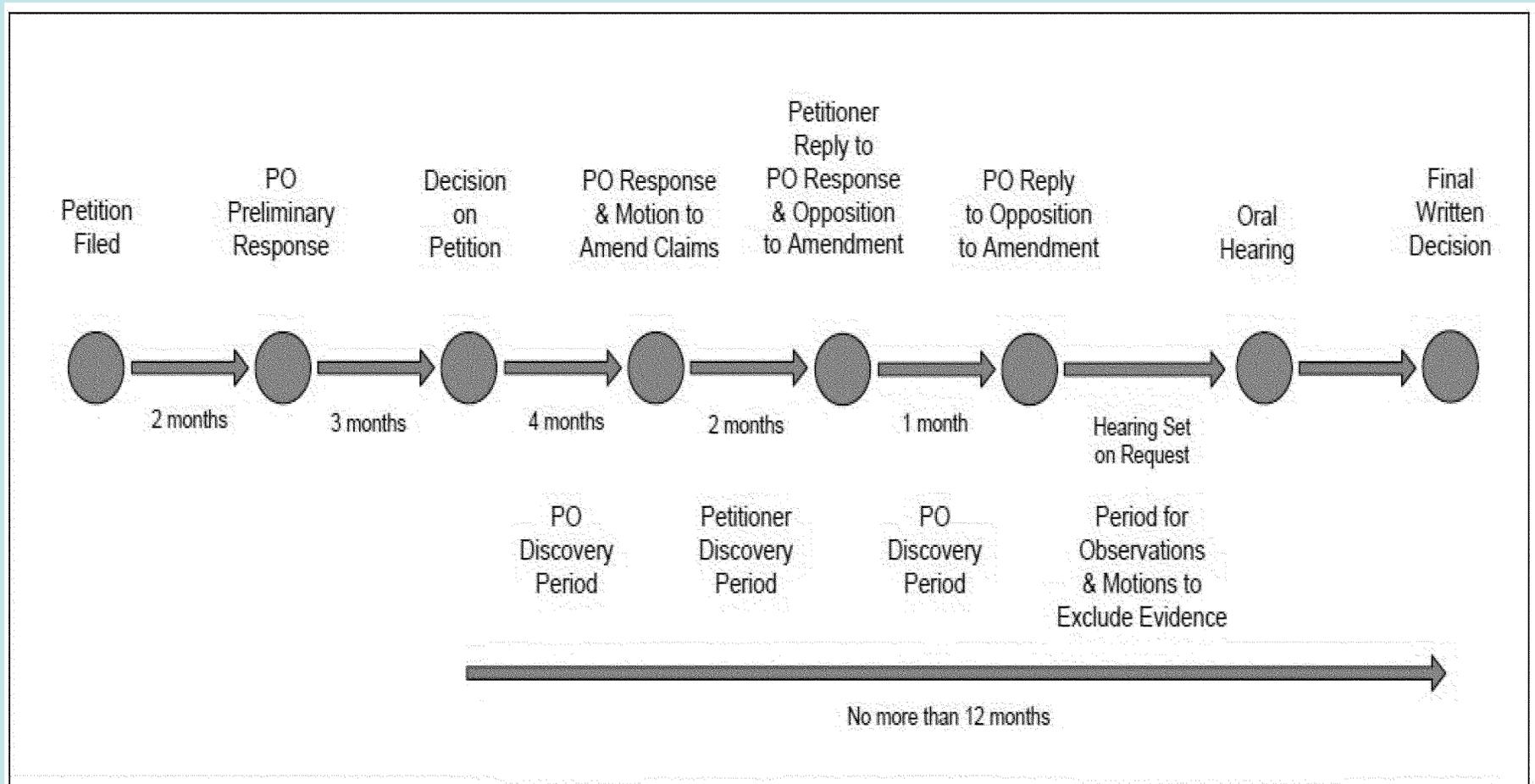
- **INTERFERENCES (BOARD)**

SUNSET: REQUIRES APPLICATION HAVING PRIORITY PRIOR TO 3/16/2013, AND INVENTION CLAIM HAVING SUPPORT IN THAT APPLICATION. (LAST INTERFERENCE SHOULD TERMINATE CIRCA 2032.)

THE NEW BOARD TRIALS

- PGR – Post Grant Review
- IPR – Inter Partes Review
- CBM – Covered Business Methods
- DER – Derivation
- COMMON PROCEDURES AND
TIMELINES APPLY
- INITIATED BY THIRD PARTY PETITION

PTO EXEMPLARY TIMELINE



PGR, IPR COMPARISON

PROCEEDING	PGR	IPR
WHEN AVAILABLE	BEFORE 9 MONTHS (FROM DATE OF PATENT ISSUANCE)	AFTER 9 MONTHS (FROM DATE OF PATENT ISSUANCE)
BURDEN OF PROOF FOR GRANT OF PETITION	“MORE LIKELY THAN NOT” (A CLAIM INVALID)	“REASONABLE LIKELIHOOD” (A CLAIM INVALID)
SCOPE OF REVIEW	ALL - 102, 103, 112, 251 (120)	PUBLISHED PRIOR ART 102, 103 (120)
ESTOPPEL DUE TO FINAL DECISION	“raised or reasonably could have raised”	“raised or reasonably could have raised”

PGR, CBM COMPARISON

PROCEEDING	PGR	CBM
WHEN AVAILABLE	BEFORE 9 MONTHS (FROM DATE OF PATENT ISSUANCE)	AFTER PETITIONER SUED OR CHARGED WITH INFRINGEMENT
SUNSET	NONE	8 YEARS AFTER CBM REGS PROMULGATED
SUBJECT MATTER LIMITATIONS	NONE	Claim for data processing for managing money and not defining a “technological invention”
ESTOPPEL	“raised or reasonably could have raised”	“raised”

PGR, IPR, CBM – DER COMPARISON

PROCEEDING	IPR	PGR, CBM	DER
JUDICIAL REVIEW	141 CAFC APPEAL (NO DISTRICT CIVIL ACTION)	141 CAFC APPEAL (NO DISTRICT CIVIL ACTION)	141 CAFC APPEAL OR 146 DISTRICT COURT CIVIL ACTION
COST FOR PETITION TO INSTITUTE PROCEEDING	\$27,200 (20 CLAIMS)	\$35,800 (20 CLAIMS)	\$400

DERIVATION PETITION REQUIREMENTS

- PETITIONER MUST HAVE A PENDING APPLICATION
- PETITION FILED WITHIN 1 YEAR OF PATENT CLAIM PUBLICATION DATE
- PETITIONER'S PENDING APPLICATION MUST HAVE A CLAIM THAT IS "to an invention that is the same or substantially the same as the earlier application's claim"
- PETITION MUST BE "supported by substantial evidence."
- "Director *may* institute" (DISCRETIONARY)

SUMMARY

- LAW OF PATENTABLE SUBJECT MATTER COMING INTO “FOCUS”
- USPTO REORGANIZED TO BRIDGE THE PATENT CORRECTION GAP BETWEEN REEXAMINATION AND THE COURTS

THE END THANK YOU!

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