

Topics on Post Grant Review

2012 MIPLA Stampede

Tim Bianchi, J.D., M.S.E.E.

Topics

- * Comparison Post Grant Options pre and post AIA
 - * Emphasis on PGR/IPR/EPX
 - * Not a detailed review of proposed rule changes
- * How AIA Post Grant Review Fits into the Big Picture of Prosecution, Reexam and Litigation
- * Reexam vs. Litigation
 - * *Marine Polymer v. HemCon* & Amendments for Intervening Rights
 - * *In re Baxter* & the clash between administrative and court based determinations

Overview on Post Grant Options pre and post AIA

Overview of Pre and Post AIA Post Grant Options

Pre-AIA

- * *Ex parte* reexam
- * *Inter partes* reexam
- * Reissue
- * Interference

Post-AIA

- * *Ex parte* reexam
- * ~~*Inter partes* reexam~~
- * Reissue
- * ~~Interference Derivation~~
- * Post Grant Review
- * *Inter Partes* Review
- * Covered Business Method Patents
- * Supplemental Examination

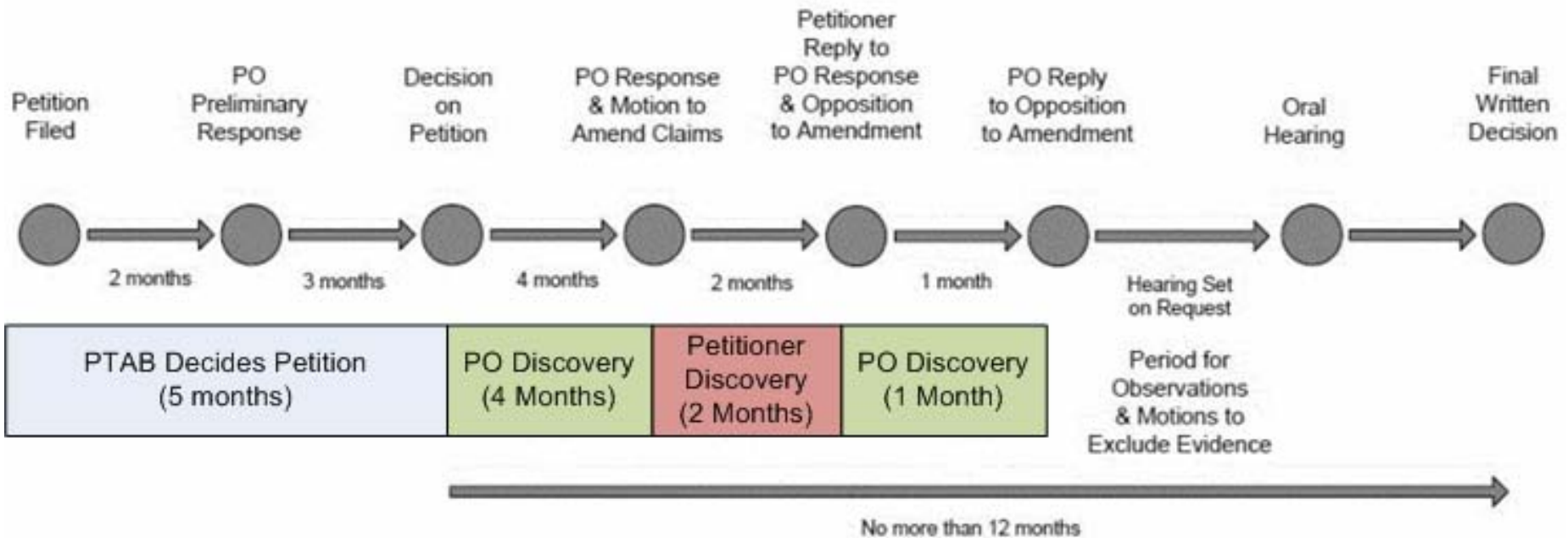
So Long, *Inter Partes* Reexam!*

- * After September 16, 2012 (4 months from now!!!):
 - * *Inter partes* reexams ordered, which are based on requests pre-September 16, 2012 will be governed by *inter partes* reexam statutes and rules
 - * will remain in CRU until resolved (not going to PTAB)
 - * Reasonable likelihood standard used – not SNQ
 - * Requests on or after September 16, 2012 **will NOT be granted.**
- * (*source: “*Central Reexamination Unit and the AIA* “ by Remy Yucel, Director, CRU - spring AIPLA meeting)

To Initiate a Proceeding

Post-Grant Review	Inter Partes Review	Ex Parte Reexam
More likely than not that at least 1 of the claims challenged is unpatentable OR Petition raises a novel or unsettled legal question important to other patents/applications	Director determines that there is a reasonable likelihood that Petitioner will prevail w.r.t. at least 1 claim challenged	Substantial New Question of Patentability
Must be Petitioned within 9 months of Issue of the Patent	Must wait until later of 9 months after Issue or completion of ordered PGR AND must be less than one year after served with infringement complaint	No timing limitations

Review Timing



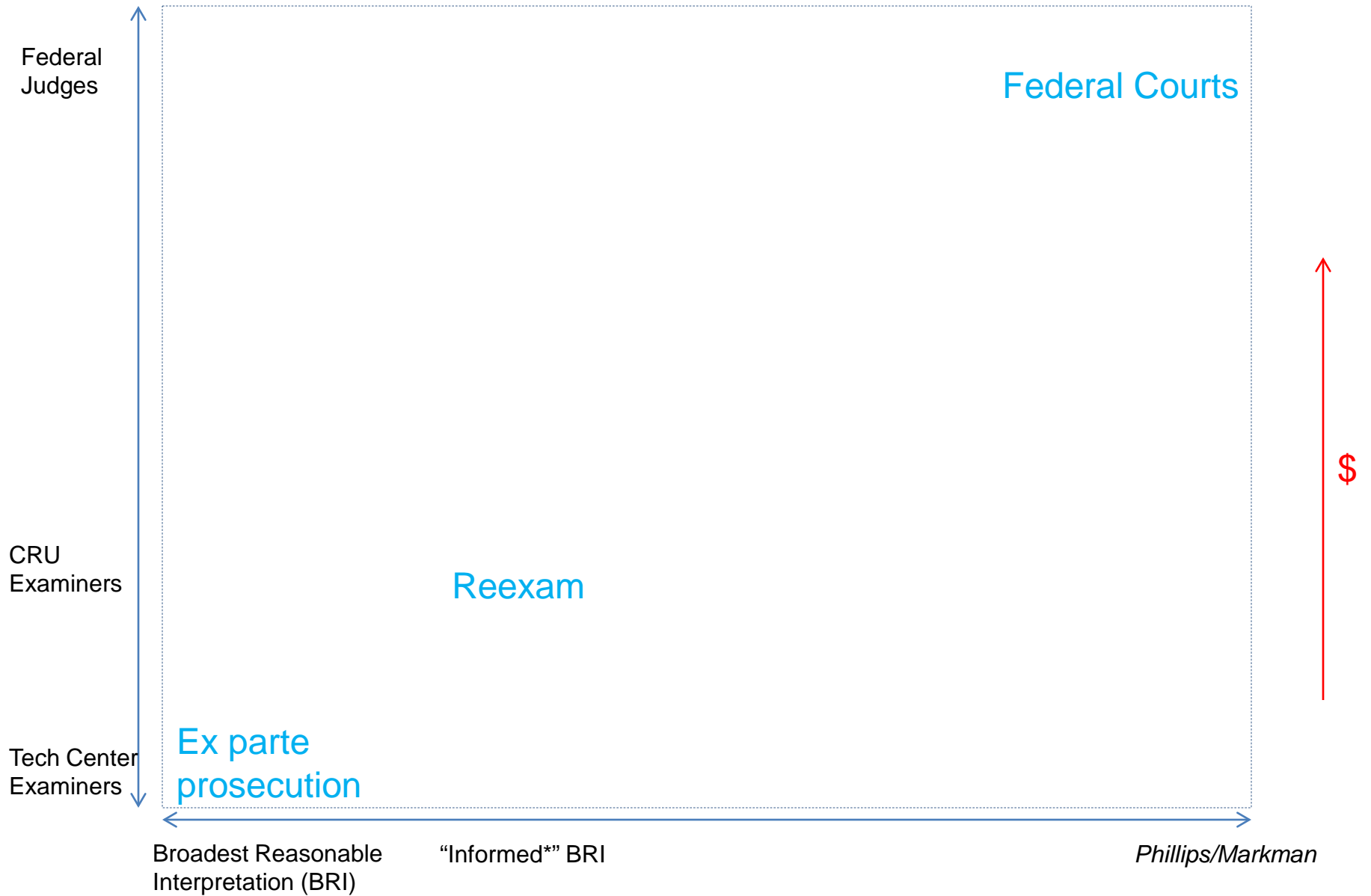
Estoppel

Post-Grant Review	Inter Partes Review	Ex Parte Reexam
<p>Estoppel in the Office: -if final written decision re a claim, and w.r.t. that claim on any ground <i>Petitioner raised or reasonably could have raised</i> during the PGR</p> <p>Estoppel in Civil Actions: -(same)</p>	<p>Estoppel in the Office and in Civil actions is essentially the same standard as for PGR, but pertains to issues in the IPReview instead of the PGR)</p>	<p>None</p>

Amendments

- 35 USC 326(d)/316(d)
 - PO gets 1 motion to amend by
 - Cancellation of any challenged claim
 - For each challenged claim, propose a reasonable number of substitute claims
 - Additional Motions to Amend
 - Only by joint request of PR and PO in settlement
 - By request of PO upon showing of good cause/(rules of director for IPReview)
 - Must be narrowing and cannot introduce new matter

The Big Picture of Prosecution, Reexam/PGR and Litigation



(* Informed with admissions, court documents and enhanced document production)

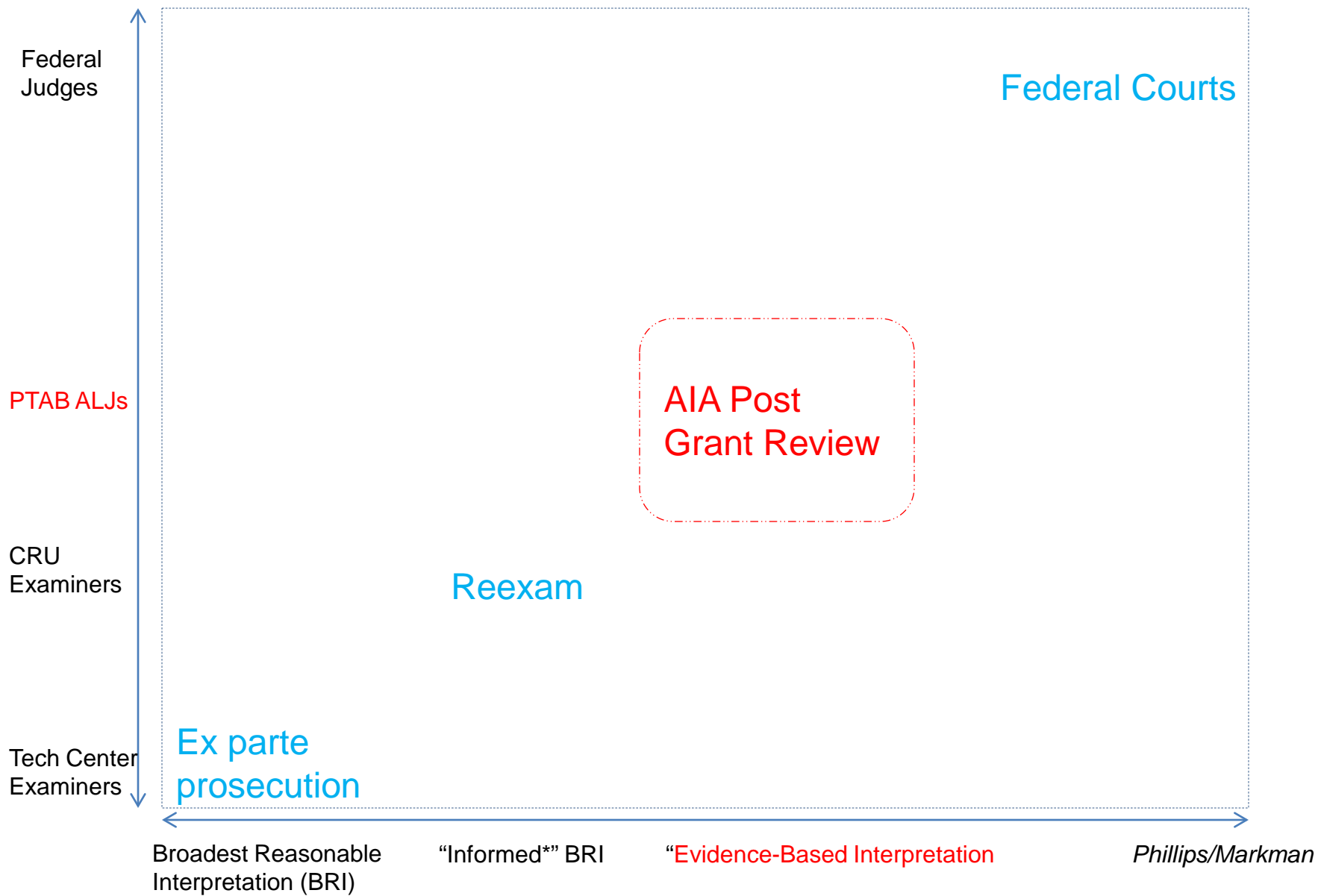
The Big Picture of PGR: Worlds Apart from *Ex Parte* Reexam

Ex Parte Reexam

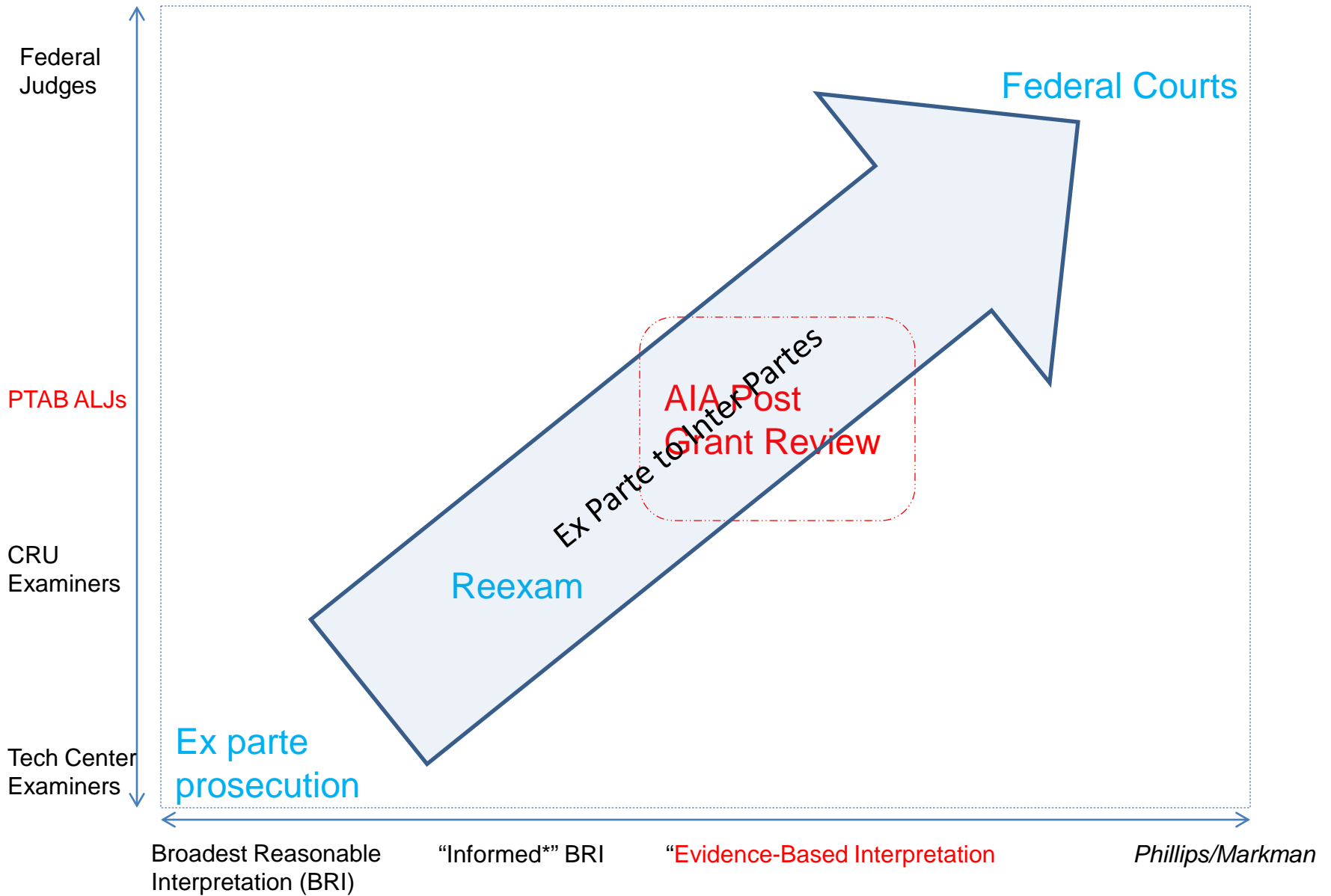
- * *Ex parte*
 - * Patent Owner-Centric
- * CRU
 - * Examiners
 - * Paper practice
 - * Prosecution-like
 - * Declaration-based evidence
- * Estoppel relatively weak
- * Lower Cost

Post Grant Review

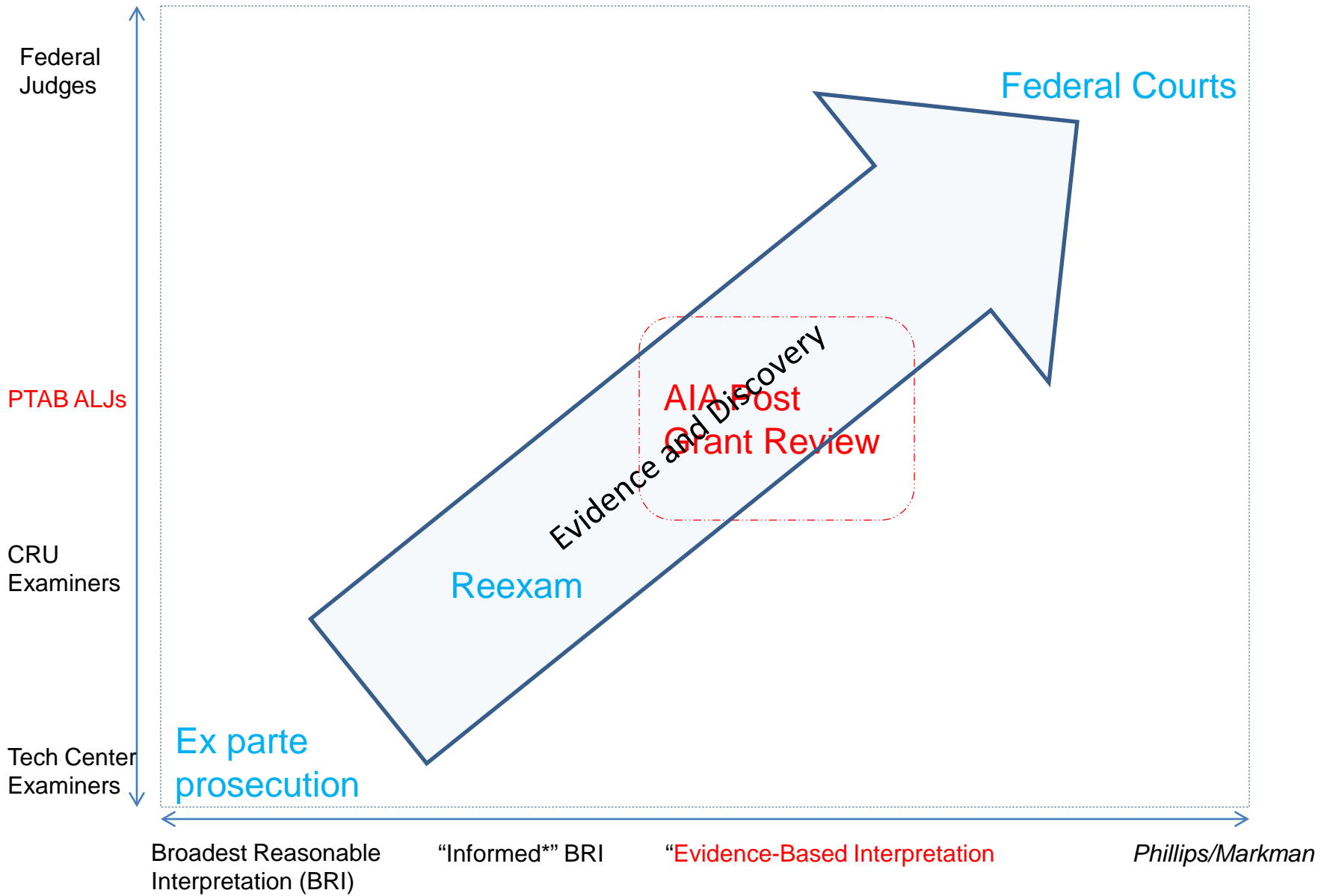
- * *Inter partes*
 - * Both Parties Participate
- * PTAB
 - * ALJ's
 - * Motion Practice
 - * Adversarial
 - * Rich Evidence and Discovery
- * Estoppel relatively strong
- * Higher Cost



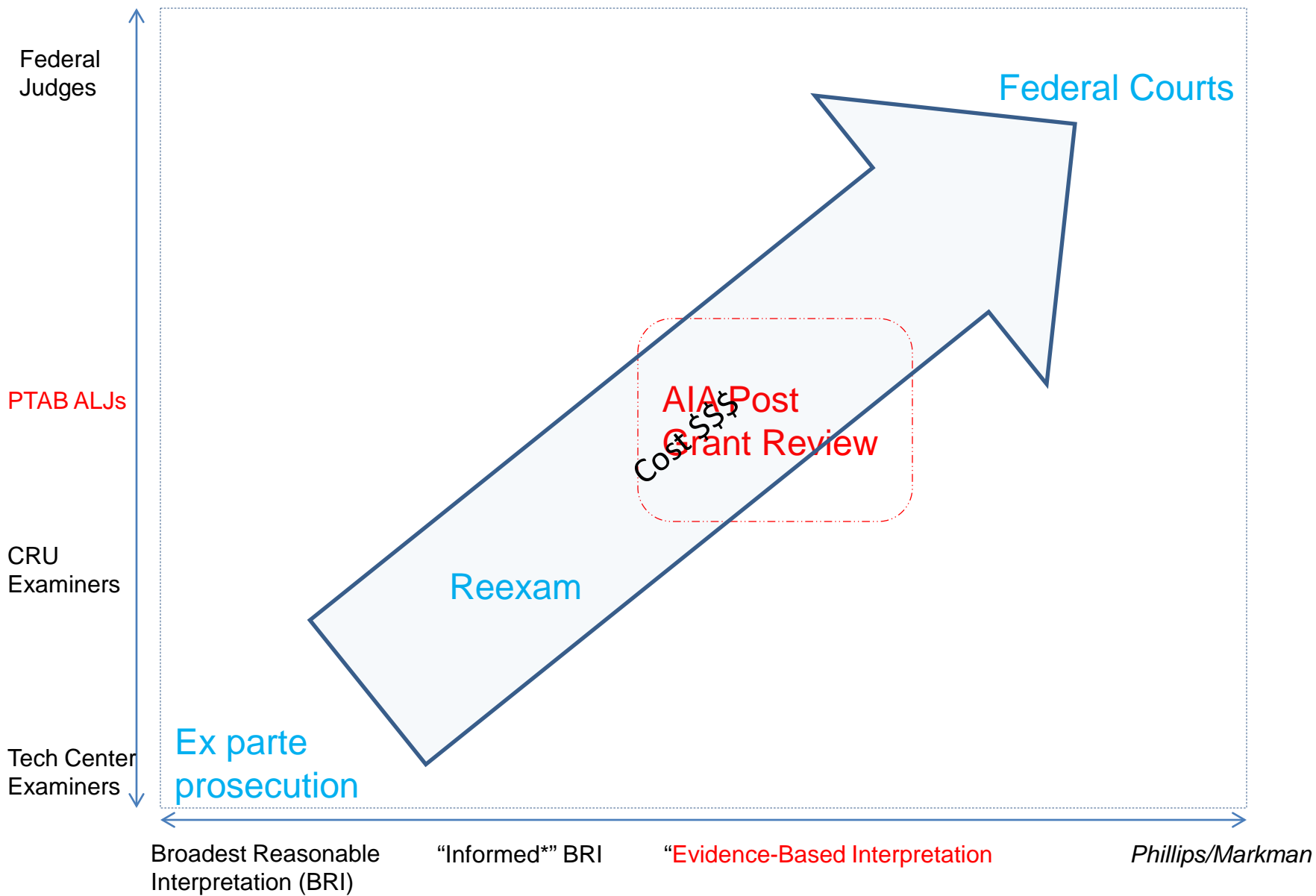
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Reexam vs. Litigation

Different standards for interpretation and for burden of proof

Ex Parte Prosecution & Reexam

- * Interpretation
 - * Broadest reasonable interpretation
 - * *In re Yamamoto*, 740 F.2d 1569, 1571 (Fed. Cir. 1984)
- * Burden of Proof
 - * Preponderance of the evidence

Litigation

- * Interpretation
 - * *Phillips/Markman*
- * Burden of Proof
 - * Clear and convincing evidence

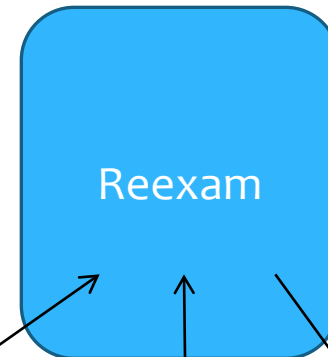
Phillips v. AWH (en banc)

- * Claims
 - * Typical “statute” interpretation
 - * Doctrine of claim differentiation
- * Specification
 - * Primary basis (again)
 - * lexicography
 - * Intentional disclaimer
 - * Examination in light of Spec
- * File History
 - * Intrinsic Evidence
 - * Less useful than Spec for lack of clarity
 - * May exclude interpretations disclaimed during prosecution
- * Dictionaries, Expert Testimony, Inventor Testimony, Treatises
 - * Extrinsic Evidence

Example of Shifting Standards

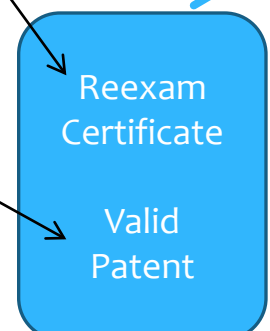
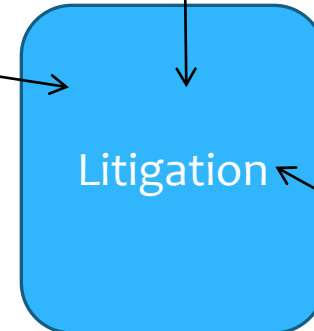
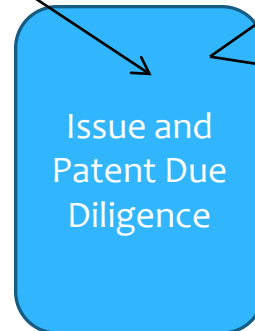
Broadest
Reasonable
Interpretation

Preponderance of
Evidence Standard



Phillips/Markman
Construction

Clear and
Convincing
Evidence Standard



Marine Polymer v. HemCon and
Amendments for Intervening
Rights

B4 (Official Form 4) (12/07)

**United States Bankruptcy Court
District of Oregon**

In re HemCon Medical Technologies, Inc.

Debtor(s)

Case No.

Chapter

11

LIST OF CREDITORS HOLDING 20 LARGEST UNSECURED CLAIMS

Following is the list of the debtor's creditors holding the 20 largest unsecured claims. The list is prepared in accordance with Fed. R. Bankr. P. 1007(d) for filing in this chapter 11 [or chapter 9] case. The list does not include (1) persons who come within the definition of "insider" set forth in 11 U.S.C. § 101, or (2) secured creditors unless the value of the collateral is such that the unsecured deficiency places the creditor among the holders of the 20 largest unsecured claims. If a minor child is one of the creditors holding the 20 largest unsecured claims, state the child's initials and the name and address of the child's parent or guardian, such as "A.B., a minor child, by John Doe, guardian." Do not disclose the child's name. See 11 U.S.C. § 112; Fed. R. Bankr. P. 1007(m).

(1)	(2)	(3)	(4)	(5)
<i>Name of creditor and complete mailing address including zip code</i>	<i>Name, telephone number and complete mailing address, including zip code, of employee, agent, or department of creditor familiar with claim who may be contacted</i>	<i>Nature of claim (trade debt, bank loan, government contract, etc.)</i>	<i>Indicate if claim is contingent, unliquidated, disputed, or subject to setoff</i>	<i>Amount of claim [if secured, also state value of security]</i>
Marine Polymer Technologies 107 Water St. Danvers, MA 01923	Sergio Finkielstein Marine Polymer Technologies 107 Water St. Danvers, MA 01923 781-270-3200	Judgment	Contingent Disputed	34,200,000.00
Ryan Kromholz & Manion, S.C. POB 26618 Milwaukee, WI 53226	John Manion Ryan Kromholz & Manion, S.C. POB 26618 Milwaukee, WI 53226 800-686-9333	Legal Services	Disputed	1,052,273.36
Cardinal Health 200, LLC Attn: Deborah Schotz 7000 Cardinal PI Dublin, OH 43017	Deborah Schotz Cardinal Health 200, LLC Attn: Deborah Schotz 7000 Cardinal PI	Distribution contract	Contingent Disputed	1,000,000.00

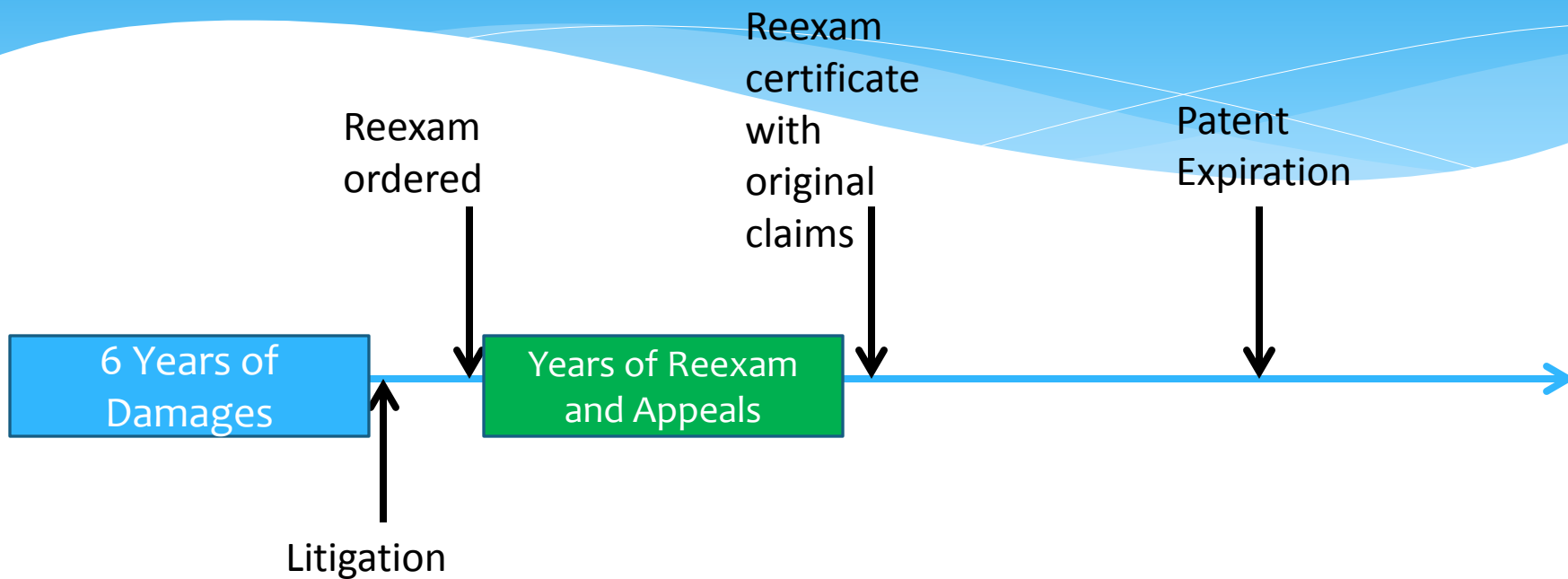
Primer on Past Damages

“Past Damages” Measured from Reexamination
Certificate if Claims Substantively Narrowed in
Reexam

Intervening Rights

- * Absolute Intervening Rights
 - * Can result in forgiveness of damages prior to issuance of reexamination certificate (“past damages”)
- * Equitable Intervening Rights
 - * Court may allow an infringer future practice of invention to allow for infringer who scaled up in reliance of invalidity of patent

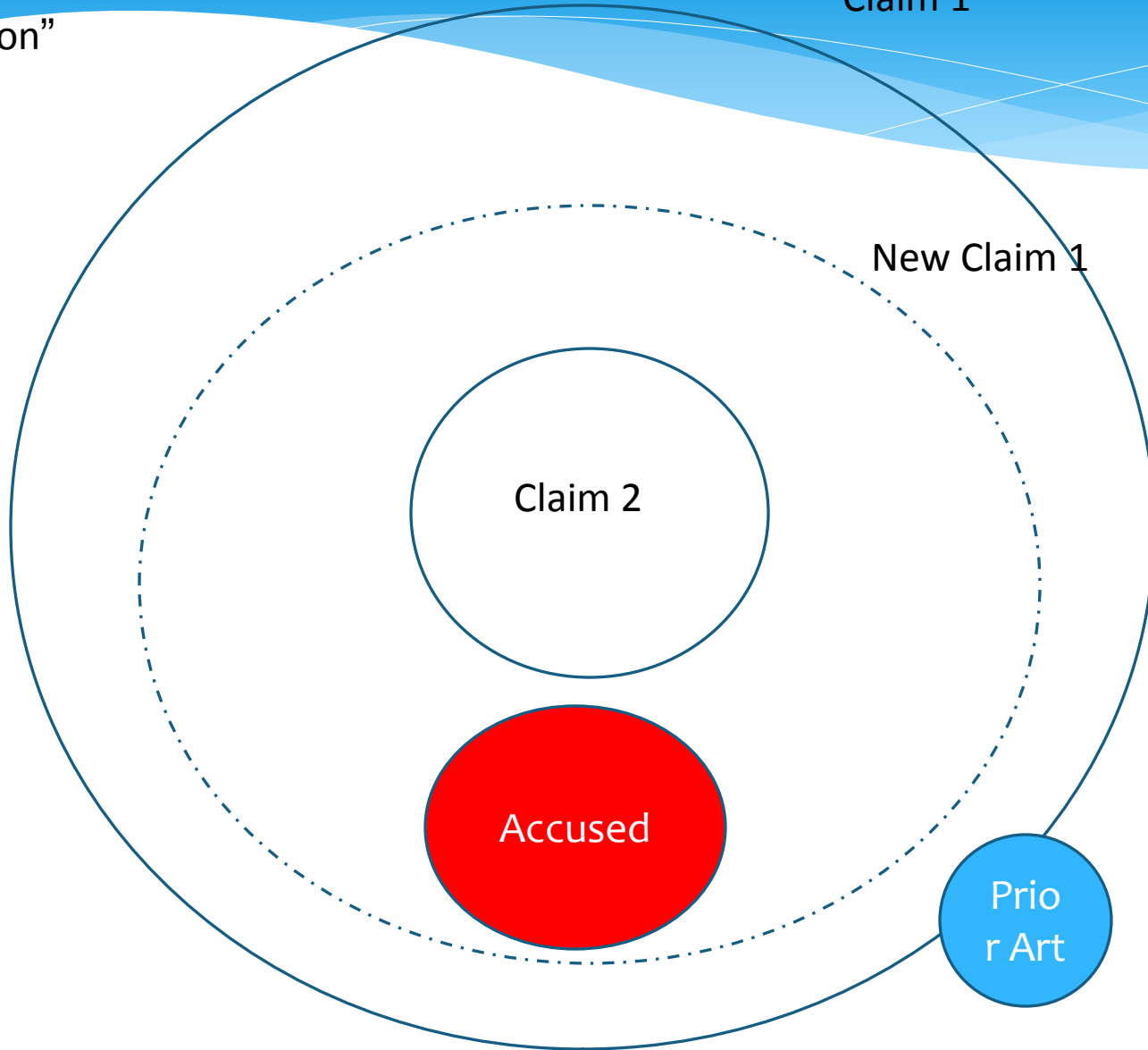
Past Damages with No Amendments



Potential Damages

“Workable Situation”

Claim 1



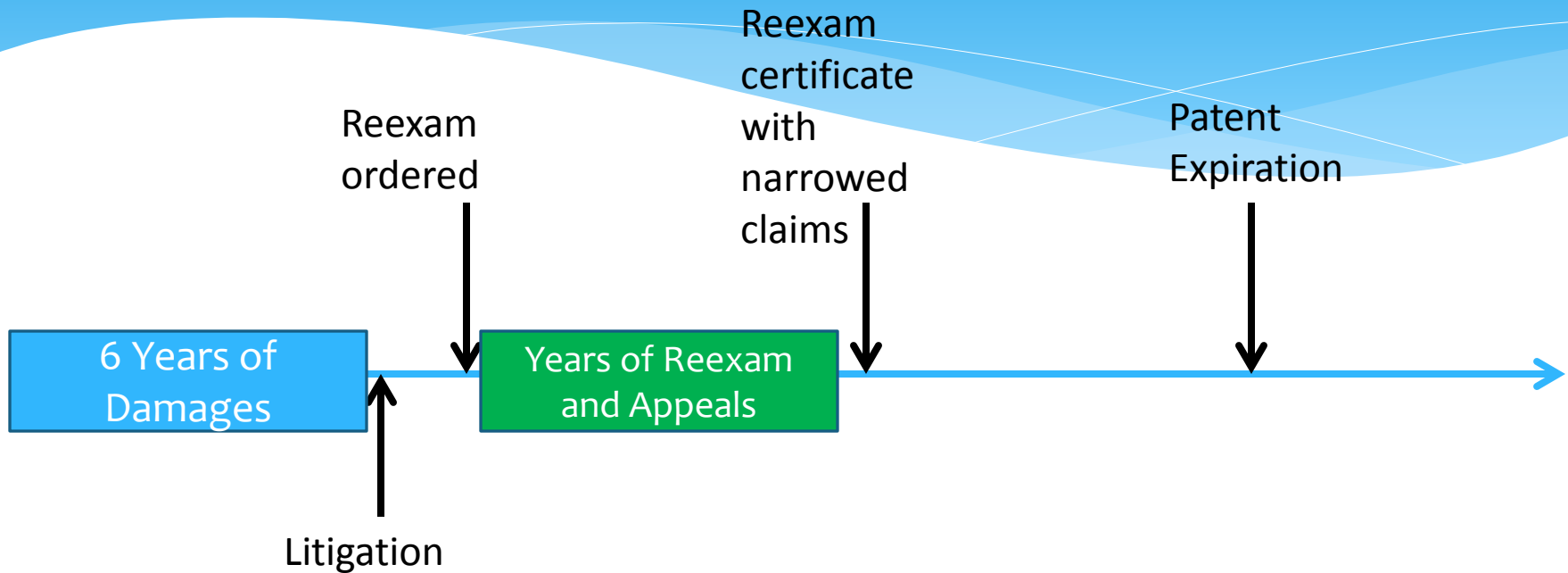
New Claim 1

Claim 2

Accused

Prior Art

“Past Damages” with Substantive Amendment



Potential Damages if no original dependent claim infringed (subject to intervening rights)

Potential Damages if original dependent claim infringed

Marine Polymer v. HemCon

- * Marine Polymer owns U.S. Pat. 6,864,245 (the '245 patent), which discloses and claims preparations of poly- β -1 \rightarrow 4-N-acetylglucosamine (“p-GlcNAc”), a naturally occurring polysaccharide **polymer** produced by organisms such as arthropods, fungi, and microalgae.
- * Purified p-GlcNAc has utility in various industrial, pharmaceutical, and biomedical applications.
- * For example, p-GlcNAc promotes hemostasis (i.e., stoppage of bleeding or hemorrhage) and is therefore useful in trauma units for treating serious wounds.

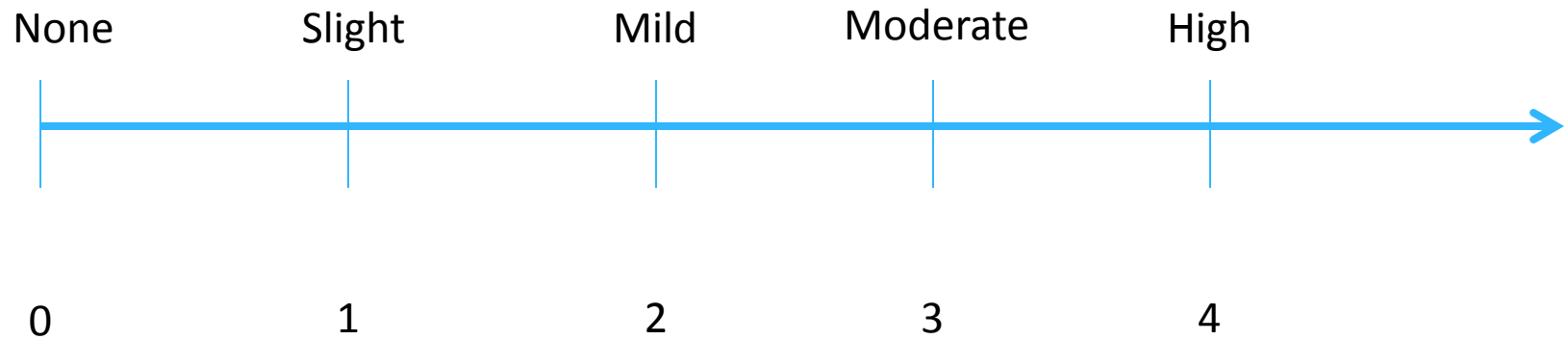
Order of Events

- * March 2006: Marine Polymer sues HemCon for infringement of claims 6, 7, 10, 11, 12, 17, and 20
 - * Single disputed claim term is “Biocompatible”
- * **August 2009: Ex Parte Reexam request 90/009,555**
- * *Markman* order: “Biocompatible” = no detectable reactivity
- * **April 2010: Examiner rejects using construction of “biocompatible” different than district court’s = “little or no detectable reactivity”**
- * August 2010: Marine Polymer argues for Dist. Ct. Construction and cancels certain dependent claims
- * September 2010: Summary Judgment + Jury Trial for Damages of \$29M + Permanent Injunction
- * **November 2010: NIRC**
- * **March 2011: Reexam Certificate Issued**
- * June 2011: Argue appeal to panel – September decision
- * Jan 2012: Cert for en banc appeal

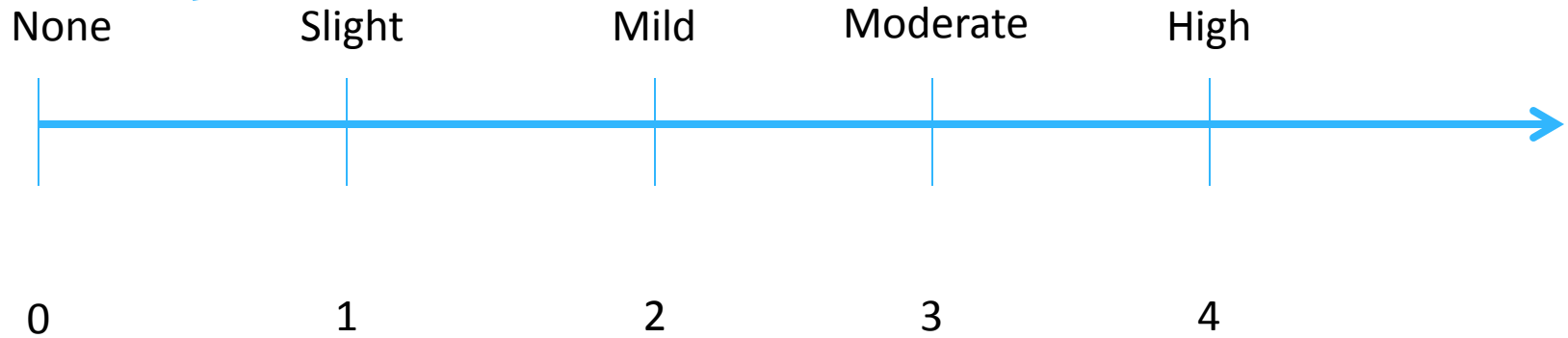
Claim 6 and “Biocompatibility”

- * 6. A **biocompatible** poly- β -1 \rightarrow 4-N-acetylglucosamine comprising up to about 150,000 N-acetylglucosamine monosaccharides covalently attached in a β -1 \rightarrow 4 conformation and having a molecular weight of up to about 30 million daltons in at which at least one N-acetylglucosamine monosaccharide has been deacetylated.

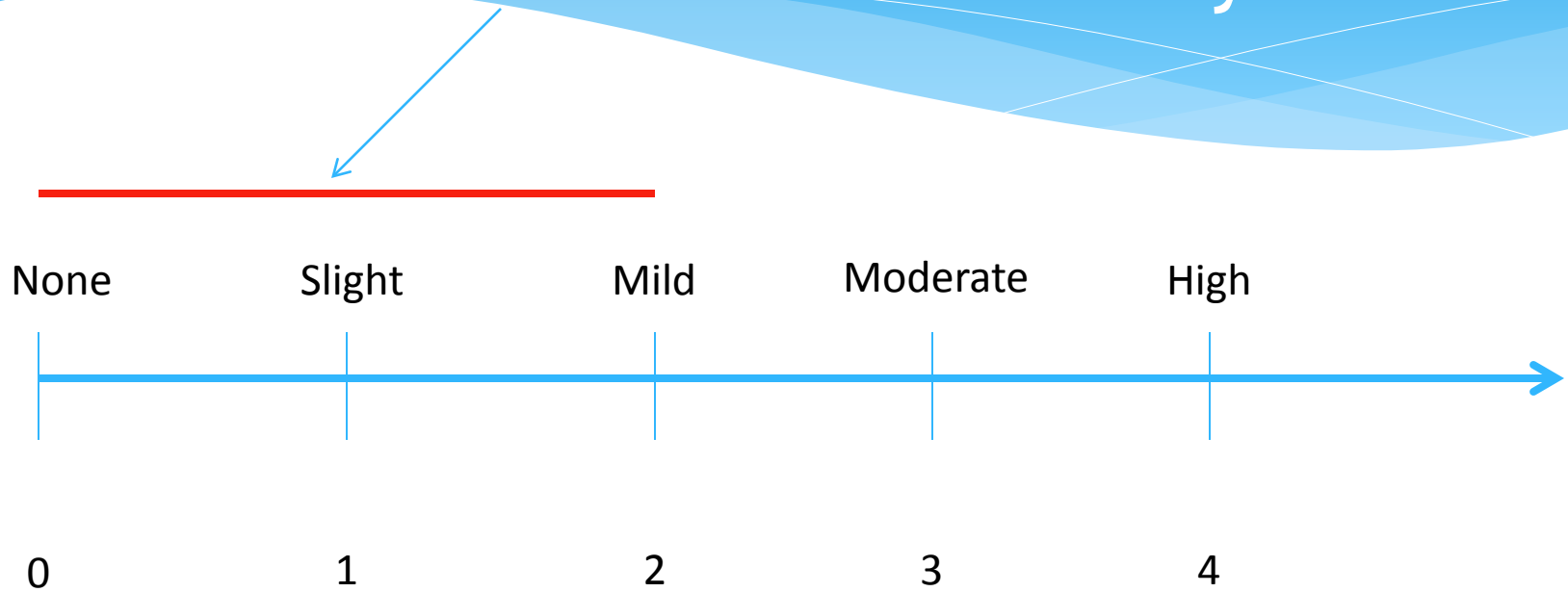
“Biocompatible” = Reactivity



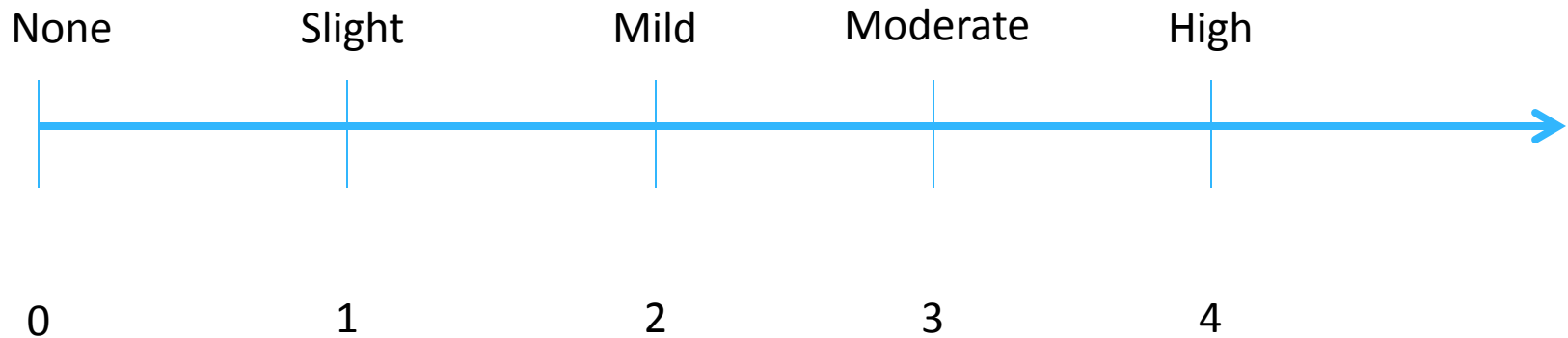
District Court *Markman*: “Biocompatible” = No Detectable Reactivity



Reexam Examiner Originally: “Biocompatible” = **Little or** No Detectable Reactivity



Reexam Examiner After Amendment*: “Biocompatible” = No Detectable Reactivity



*Cancellation of dependent claims requiring elution test scores of 1 and 2.

“Marine Polymer
Definition Issue”

Claim 6
“Biocompatible” =
Little or No
Reactivity

Claim 6
“Biocompatible” =
No Reactivity

Depende
nt claims

Accused

Prio
r Art

Original Federal Circuit Decision

- * Sept. 2011 decision
- * Panel of 3 judges
 - * Claim 1 was amended by argument, arguments were substantive (to overcome prior art), therefore intervening rights apply **DESPITE THE FACT THAT NO AMENDMENT WAS MADE TO CLAIM**
- * Should intervening rights be triggered by argument?

Federal Circuit *En Banc*

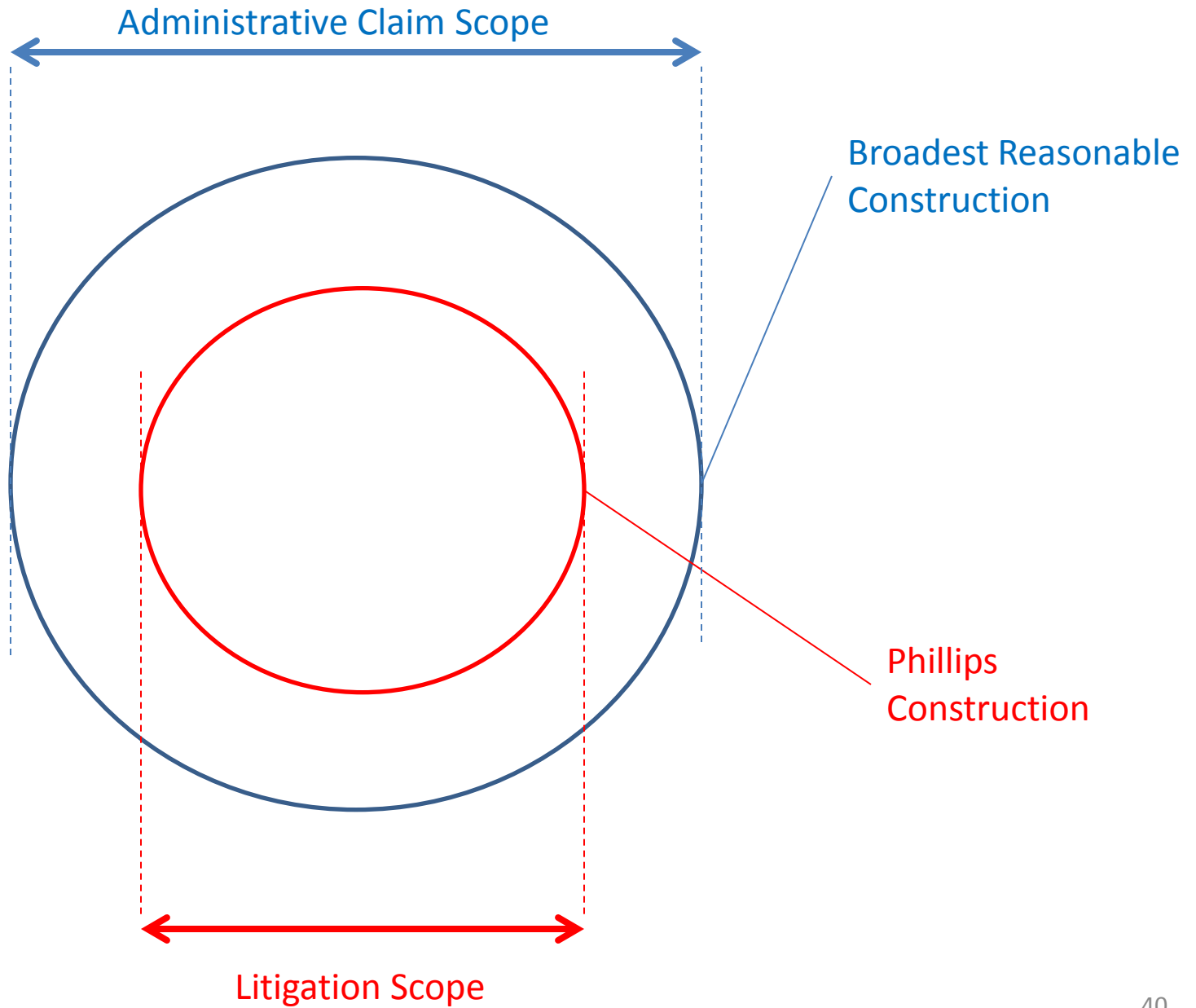
- * March 2012 *en banc* decision vacates panel decision
- * Requires actual amendment as a prerequisite to test for possible intervening rights
 - * Applies *Kaufman v. Lantech* 807 F.2d 970 (Fed. Cir. 1986) analysis for substantive change
- * Lots of *amici* briefs
- * Vigorous dissent
 - * Will encourage argument over amendment
 - * Will allow patent owner to retroactively validate claims if arguments prevail over amendment

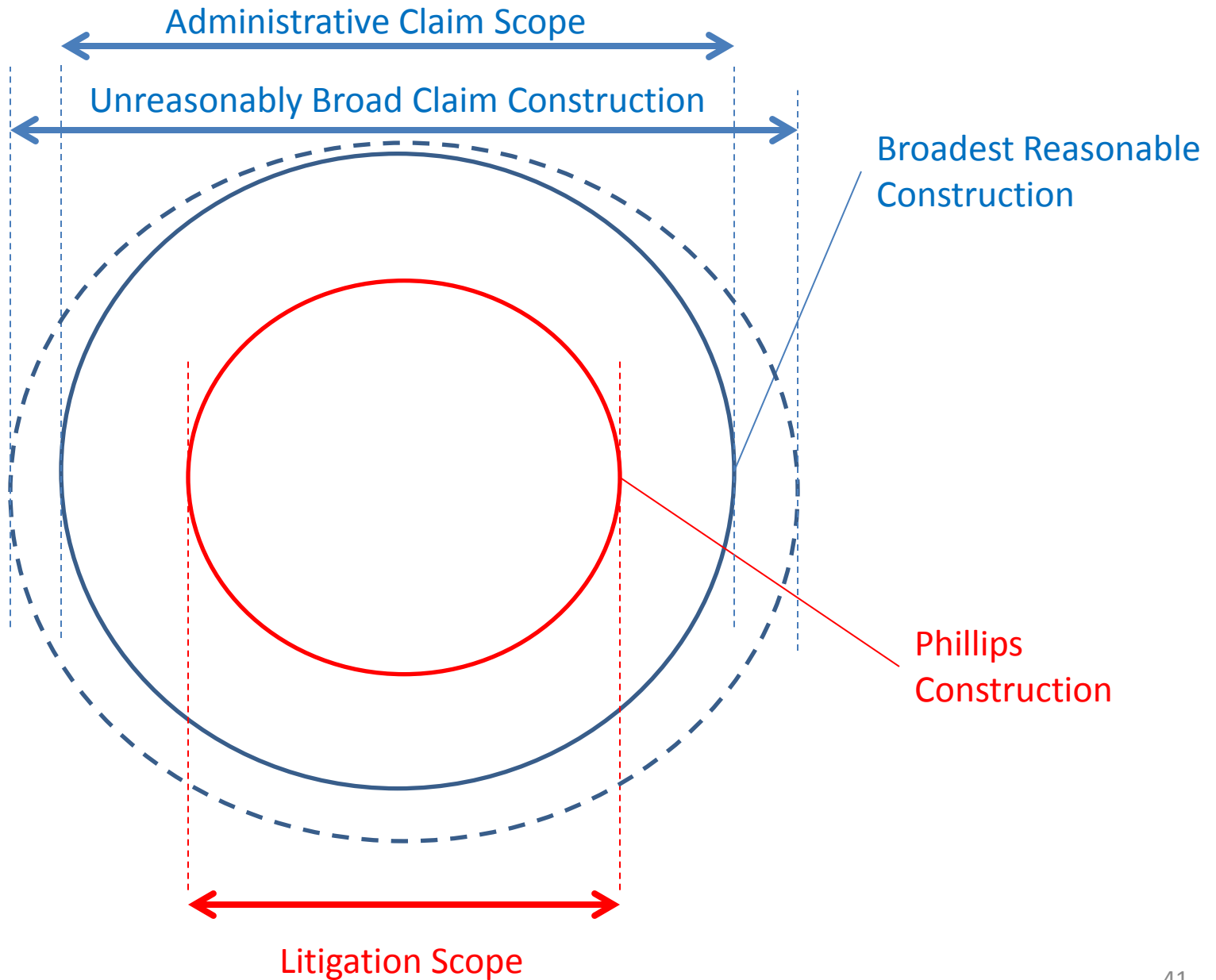
En Banc Fed. Cir.

- * March 15, 2012 *en banc* decision
 - * Step 1: Need actual amendment to claims as a first step to an intervening rights analysis
 - * Step 2: Is the amendment a substantive amendment?
- * But should the focus be on **amendment in reexam?**

BRI v. *Phillips*

- * Can you have a claim that is narrowed just because of an unreasonably broad determination in reexam/PGR?
 - * If so, then is that amendment even related to substantive change?
 - * *Phillips* interpretation need not be disturbed
- * Can you have a claim that is narrowed due to the broader interpretive doctrine of “broadest reasonable interpretation” and not change the scope of the claim in view of a *Phillips* construction?
 - * If so, then this should not constitute a “substantive change” for purposes of triggering intervening rights
- * Should “amendment” as defined by the *Marine Polymer en banc* majority even be the trigger for determination of intervening rights?





Observations

- * Arguments will be favored over amendment
 - * but they always were
- * Decision may have put more attention on “amendment” than on substantive change
 - * Amendment of dependent claims not enough
 - * *Marine Polymer* fails to better define “substantive change”

Query

- * Can one control broadest reasonable construction in reexam/PGR at the time of patent application preparation?
 - * Term definitions
 - * Clear delineation of prior art
 - * Interpretive doctrines

In Re Baxter International, Inc.

- * Federal Circuit decided May 17, 2012
- * Hemodialysis Machine that monitors and controls a number of parameters
- * When the Federal Circuit finds that references do not effectively render claims invalid in litigation, can a subsequent reexamination decision finding the claims invalid in view of at least similar references be upheld by the Federal Circuit?
- * Majority: Yes!
- * Dissent: NO!

'434 Patent

- * Baxter owns U.S. Pat 5,247,434: Method and Apparatus for Kidney Dialysis
 - * Dialysis machine with touch screen to monitor and control several parameters

Touch Screen for Dialysis

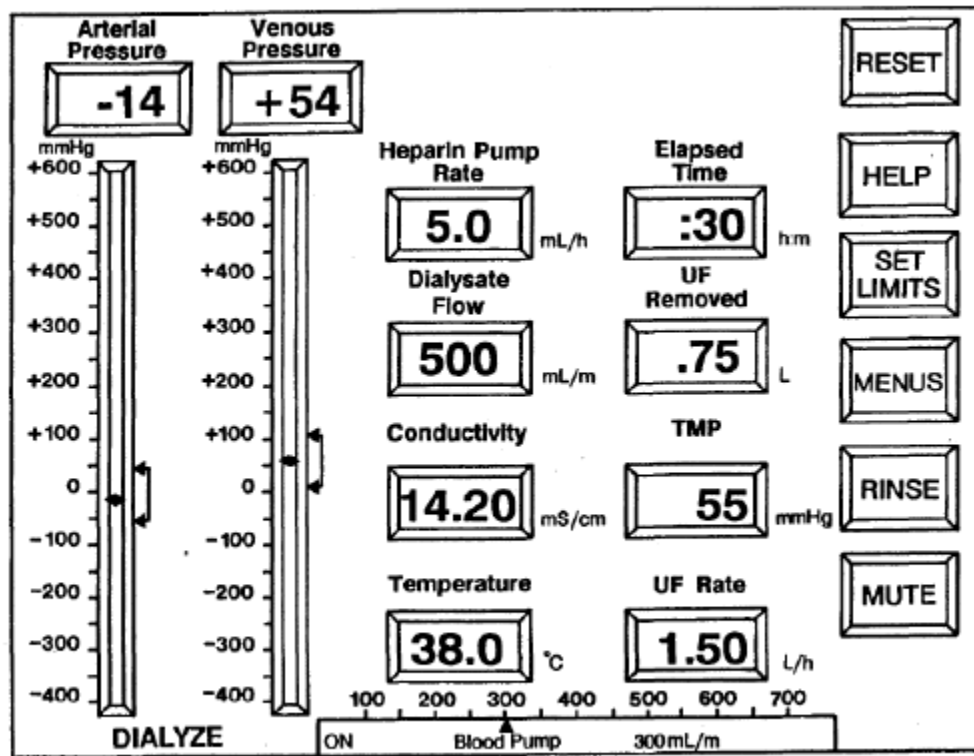


FIG. 8

Events

- * 2003: Competitor Fresenius files Declaratory Judgment action in Northern Dist. Calif
- * Jury trial with clear and convincing evidence standard that claims 26-31 were obvious
- * After trial, Baxter moves for judgment as a matter of law that claims are not invalid and district court grants motion:
 - * As a matter of law, Fresenius failed to show by clear and convincing evidence that this prior art invalidated claims
 - * CMS o8 Manual
 - * Seratron System

Appeal of Court Decision (Fed. Cir. Round 1)

- * Fresenius appeals
- * Federal Circuit affirms
- * Claims are not invalid in view of these two references

Reexam

- * 2006: PTO begins reexam of '434 patent in reexam
- * Examiner finds claims 26-31 obvious in view of similar references including, but not limited to, one used at trial
 - * Not clear from opinion if the references were completely identical
 - * CMS o8 Manual was mentioned
- * Baxter appeals to BPAI
 - * Before BPAI decides, Fresenius case is decided which finds claims not invalid
 - * Baxter petitions examiner to consider favorable finding in Fresenius case – that is denied, but BPAI was ordered to consider the Fresenius case
 - * Even in light of Fresenius decision, BPAI uphold examiner's rejection of claims

BPAI Justification for Rejecting Claims

- * Even though the Fresenius decision did not find the claims invalid in view of the references, a lower standard of proof (clear and convincing) and (more liberal) broadest reasonable interpretation standard applies in reexam ; hence the Office is not bound by the court's determination (citing *Ethicon v. Quigg*, 849 F.2d 1422, 1429 (Fed. Cir. 1988) and *In re Swanson*, 540 F.3d 1368, 1377 (Fed. Cir. 2008))
- * Now Baxter appeals this decision to the Federal Circuit which is the present case.

Fed. Cir. Upholds BPAI on rejection in Reexam – Despite having earlier upheld Dist. Court on lack of obviousness in Round 1

- * “[T]he PTO in reexamination proceedings and the court system in patent infringement actions “take different approaches in determining validity and on the same evidence could quite correctly come to different conclusions.’[citing *Swanson*, quoting *Ethicon*]”
- * Court seems to blame the lower burden of proof in reexam as opposed to litigation
 - * But what about *BRI v. Phillips*?

But See This . . .

Lest it be feared that we are erroneously elevating a decision by the PTO over a decision by a federal district court, which decision has been affirmed by this court, the following additional comments must be made. When a party who has lost in a court proceeding challenging a patent, from which no additional appeal is possible, provokes a reexamination in the PTO, using the same presentations and arguments, even with a more lenient standard of proof, the PTO ideally should not arrive at a different conclusion.

Blame it on differences in prior art?

- * Yet, the Court also seems to blame it on differences in prior art asserted in reexam as opposed to litigation:
- * “In this case, the patent examiner relied on new prior art that had not been raised in the prior district court proceeding. Why Fresenius did not present that prior art before the district court we do not know.”
- * “[T]his is not a case about the relative primacy of the courts and the PTO, about which there can be no dispute.”

Newman Dissents

- * “No authority, no theory, no law or history, permits administrative nullification of a final judicial decision. No concept of government authorizes an administrative agency to override or disregard the final judgment of a court. Judicial rulings are not advisory; they are obligatory.”
- * “We have found no hint that reexamination of the question of patentability is intended to override judicial resolution of the question of patentability.”

Query

- * Is patentability the same as validity?
- * Is patentability determined by the Office and validity subject to the courts?
- * In cases such as these is it possible that reexamination can fix patentability, yet preserve validity per the Court's determination of nonobviousness?

Big Takeaways

- * The AIA (PGR and Inter Partes Review) adds a new layer of post-grant administrative actions that will be adversarial and evidence based than prior post-grant options
- * If you are a **prosecutor**, regardless of whether you practice in reexam/review or not, you are involved in reexam/review by virtue of how you claim and define your inventions
- * If you are a **litigator**, you are involved in reexam/review because the interplay of litigation and reexam was dense, and is getting more complex

Questions?

- Tim Bianchi
- (612) 373-6912
- www.ReexamLink.com