Disclosure to Patent Offices: *Therasense v. Becton Dickinson*

Competition Law Association

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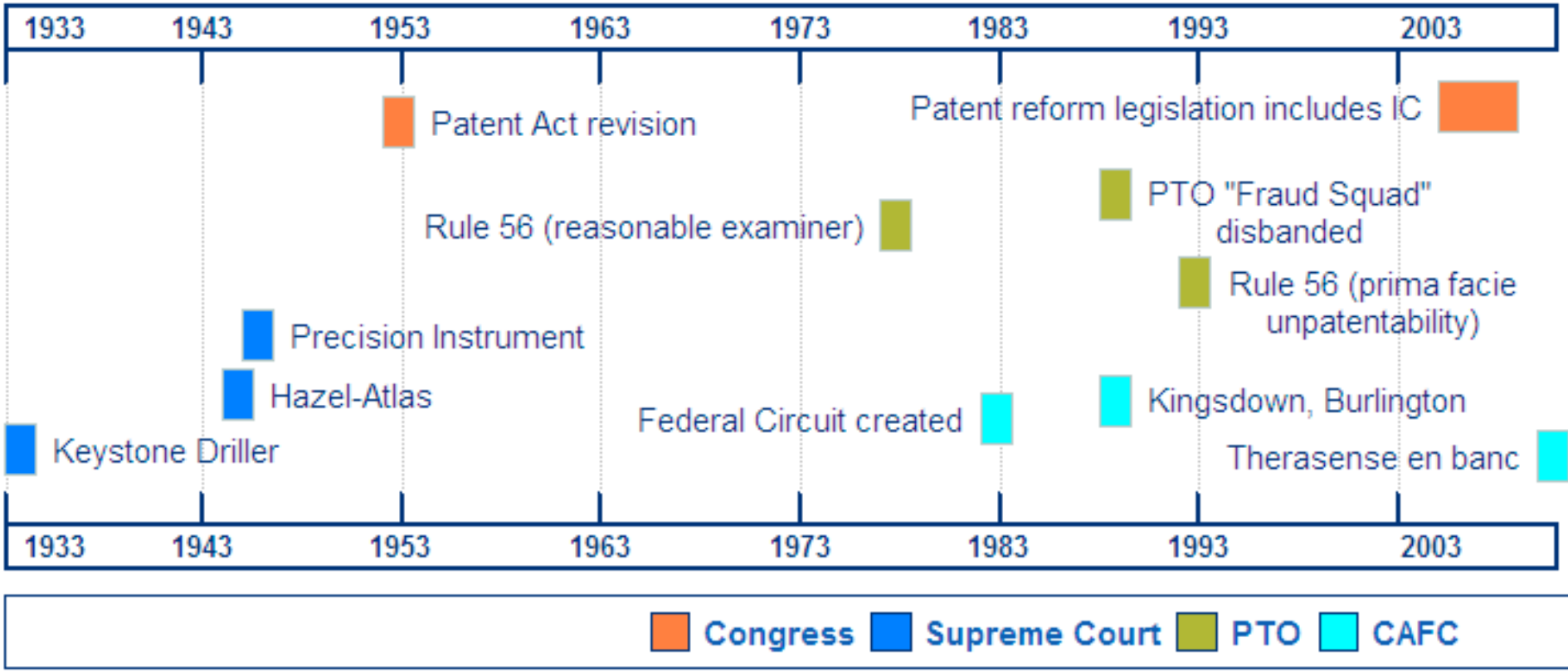
Therasense v. Becton Dickinson

Overview of the Facts

Overview of Inequitable Conduct

Inequitable Conduct Milestones



Produced on Mar 06 2011.

The Elements of Inequitable Conduct

- Materiality
- Intent
- Balancing

- Remedy

The Elements of Inequitable Conduct

- Materiality
  - But-For : “the misrepresentation was so material that the patent should not have issued”
  - Rule 56 (1992): prima facie case of unpatentability of a claim, or inconsistent with other applicant representations
  - Reasonable Examiner: substantial likelihood that a reasonable examiner would consider it important in deciding whether to allow the application to issue as a patent

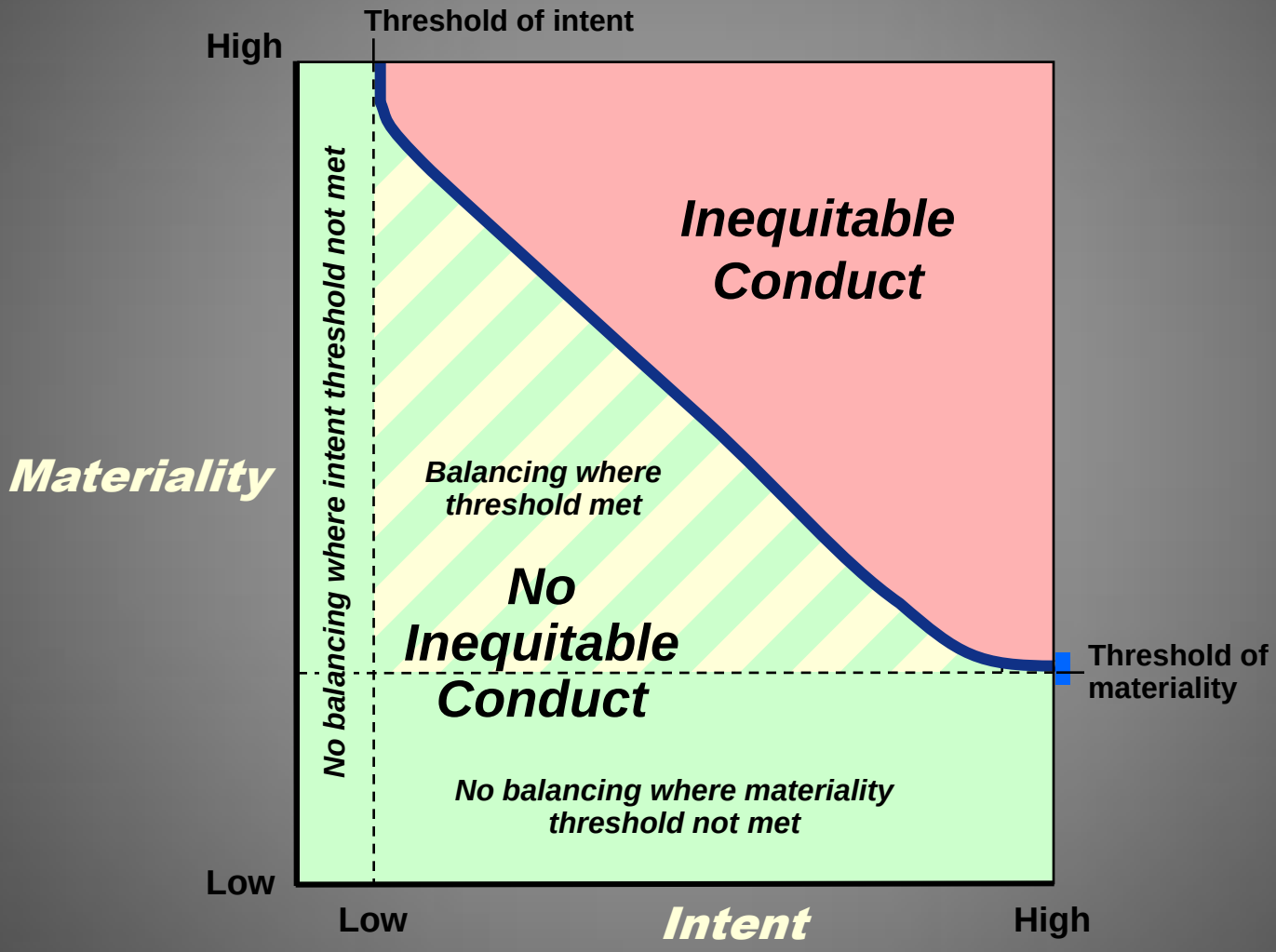
The Elements of Inequitable Conduct

- Intent
  - "Should have known"
  - "Single most reasonable inference"
  - Allowing some inference of intent from the high materiality of the withheld reference
  - Good faith explanation

The Elements of Inequitable Conduct

- Balancing
  - If materiality and intent thresholds met, is the conduct sufficiently culpable to warrant a finding of unenforceability
- Remedy
  - Just one remedy – unenforceability of whole patent

Elements of Inequitable Conduct



Source: Mammen, “Controlling the Plague…,” 29 Berkeley Tech. L.J. 1329 (2009)

Recent Cases

Materiality - Recent Cases

- Courts are looking at every aspect of patent prosecution, especially what is told (or not told) to the patent office.
  - Undisclosed interests
  - Withheld prior art
  - Co-pending applications
  - Inconsistent positions

Recent Cases

- Ferring B.V. v. Barr Labs, Inc., 437 F. 3d 1181 (Fed. Cir. 2006)
  - Undisclosed Interests
    - Ferring argued a more narrow claim interpretation than the broadest reasonable interpretation
    - Examiner asked for non-inventor expert Declarations.
    - Ferring provided 4 Decs but failed to disclose they had previously employed 3 out of 4 of the experts.
    - Court found inequitable conduct for failing to disclose the relationships.

Recent Cases

- Digital Control v. Charles Machine Works, 437 F. 3d 1309 (Fed. Cir. 2006)
  - Failed to submit reference cited from co-pending app.
  - Misstatements in a Rule 131 Declaration
  - Materiality: All standards can apply
    - Objective but-for
    - Subjective but-for
    - But it may have
    - Reasonable Examiner
    - 1992 Rule 56

Recent Cases

- McKesson Information Solutions, Inc. v. Bridge Medical, Inc., 437 F. 3d 897 (Fed. Cir. 2006)
  - Withheld rejection and reference from co-pending application
    - Disclosed co-pending application to examiner
    - Did not disclose office action and reference cited in co-pending application
    - Claims were substantially similar
    - No explanation for withholding

Recent Cases

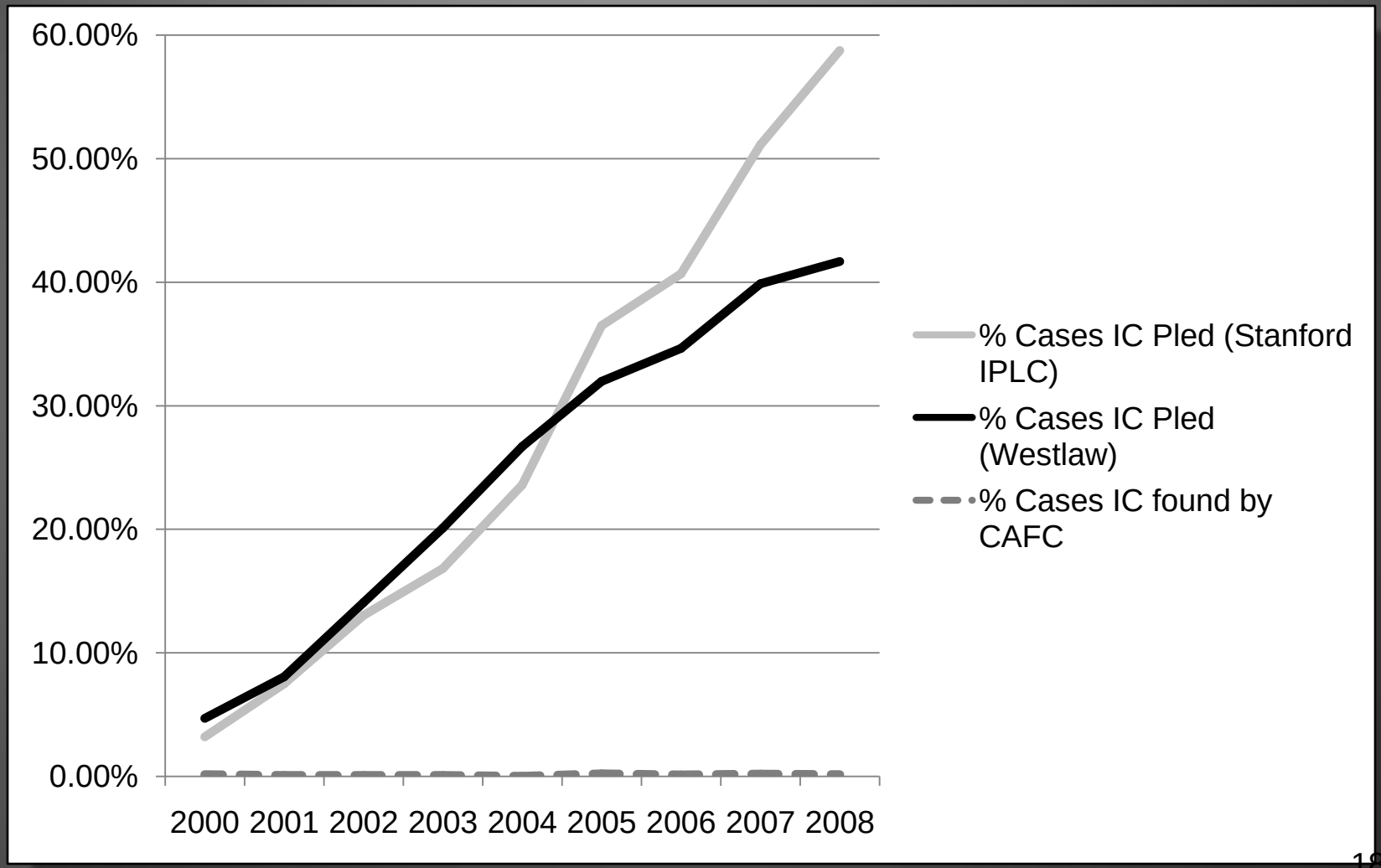
- Monsanto Co. v. Bayer Bioscience N.V., 514 F. 3d 1229 (Fed. Cir. 2008)
  - Poster child for disclosing relevant prior art
    - Bayer scientist took detailed notes of another's paper at a conference poster session
    - Bayer submitted the Abstract of the poster as prior art
    - Court found inequitable conduct for failing to disclose the highly material detailed poster notes.

Recent Cases

- Aventis Pharma S.A. v. Amphastar Pharmaceuticals, Inc., 525 F. 3d 1334 (Fed. Cir. 2008)
  - Inconsistent positions
    - To overcome prior art rejections, Aventis filed a Declaration showing a significant difference in half-lives of the claimed composition and the prior art
    - Aventis did not disclose different doses were used
    - In multiple appeals, Aventis changed their story as to why they failed to disclose
    - Court found inequitable conduct for failing to disclose the differences.

A “Plague”?

Pleading Inequitable Conduct



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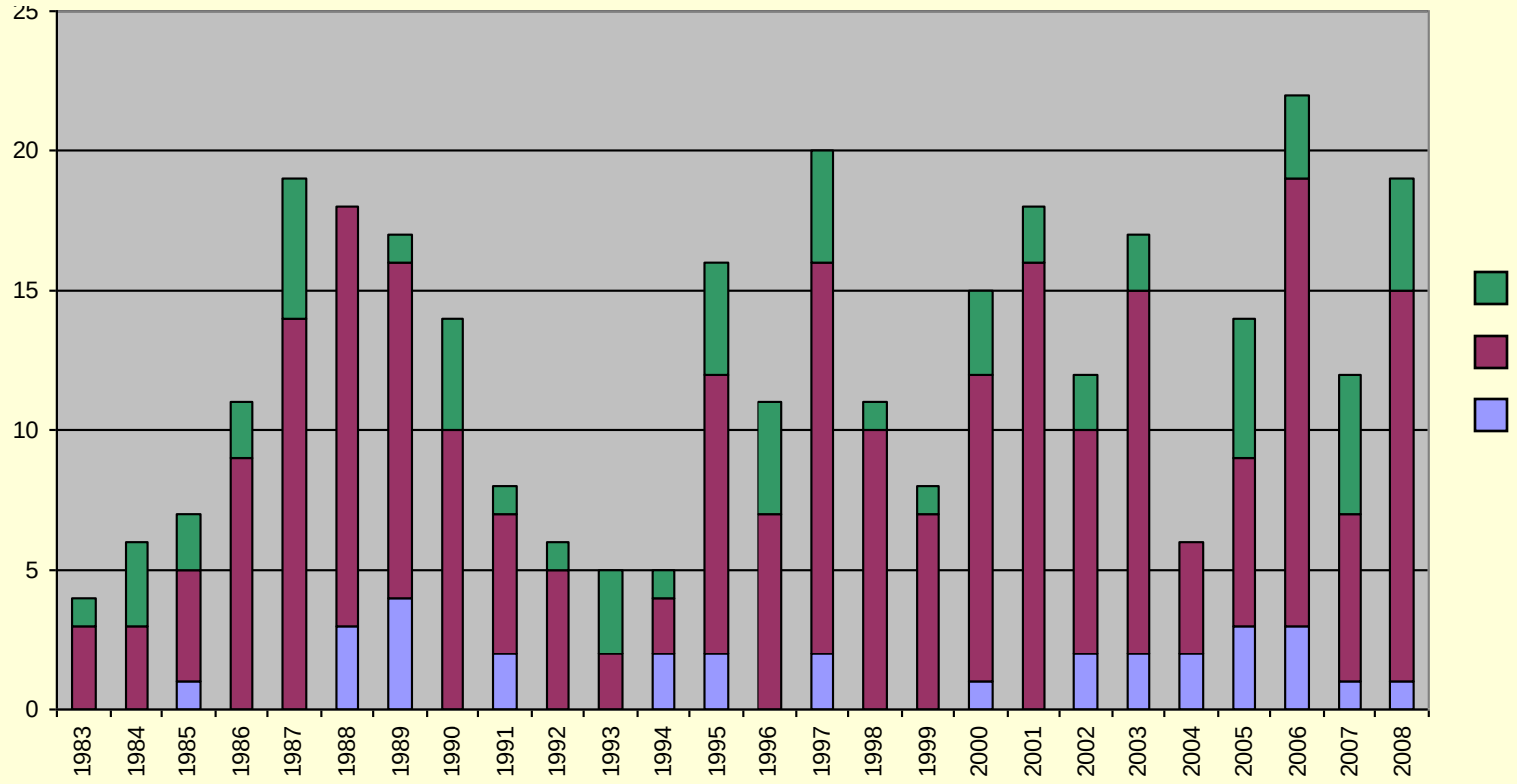
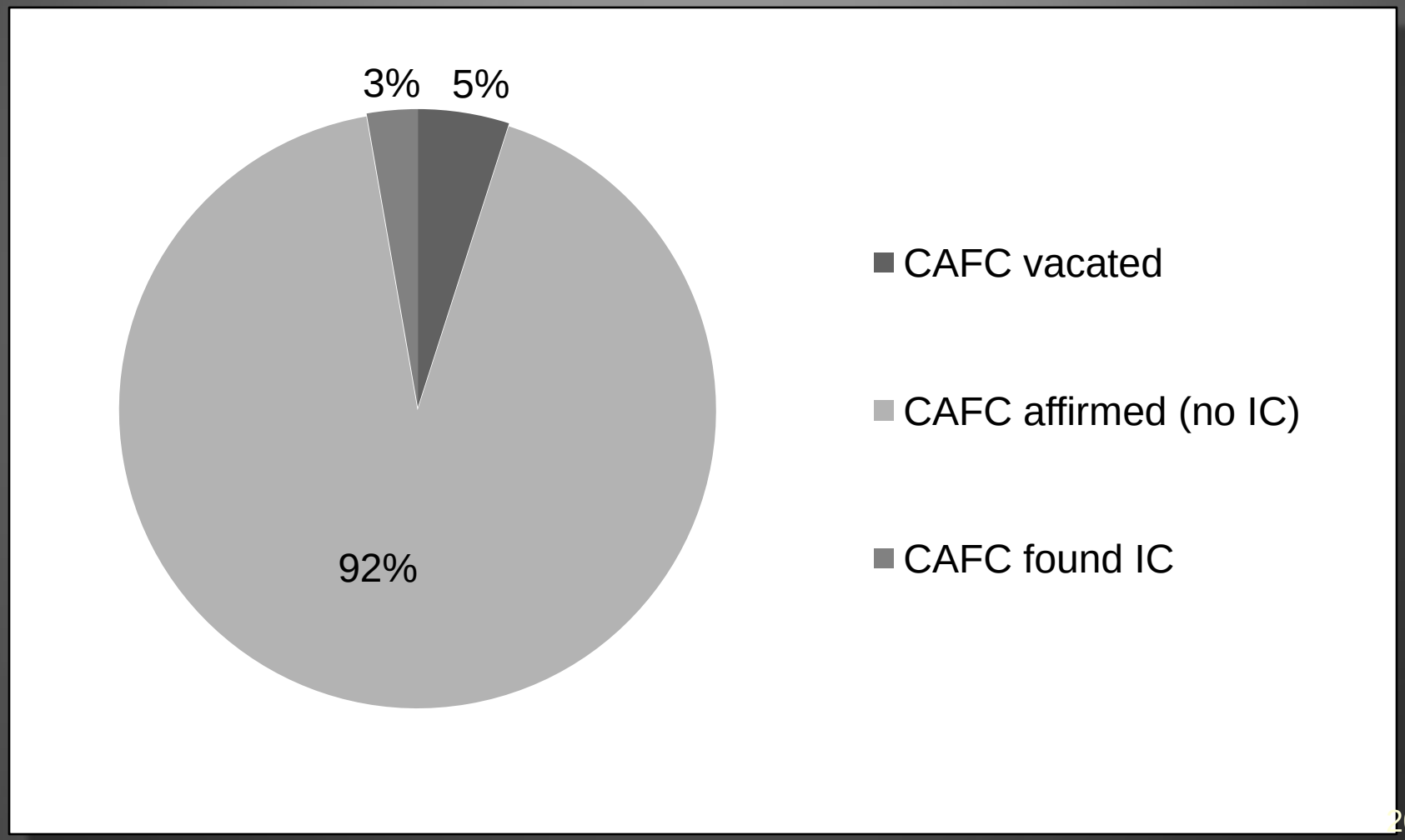
Number of CAFC Cases Addressing Inequitable Conduct



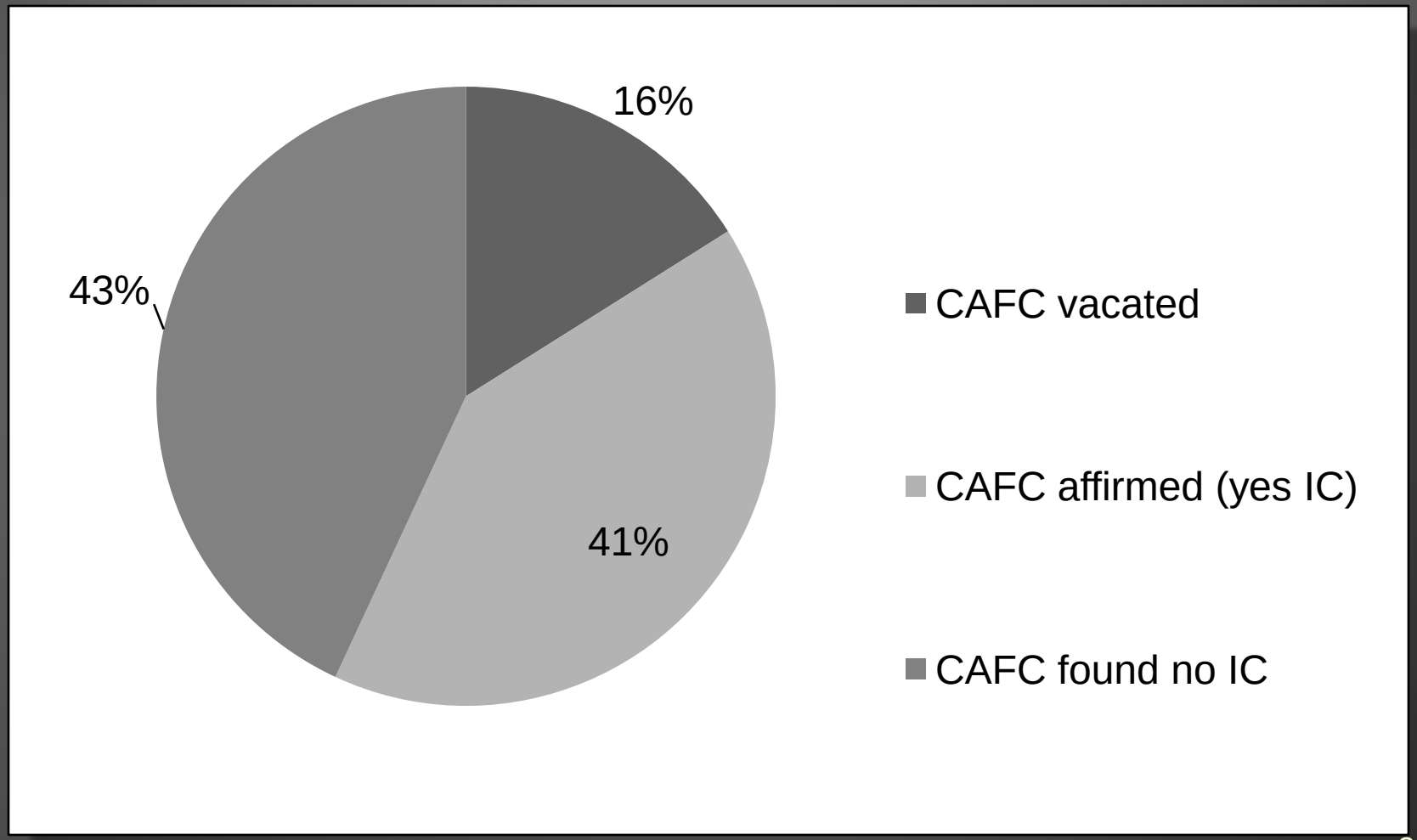
Source: Mammen, “Controlling the Plague…,” 29 Berkeley Tech. L.J. 1329 (2009)

Federal Circuit Disposition of "No IC" Rulings by District Court



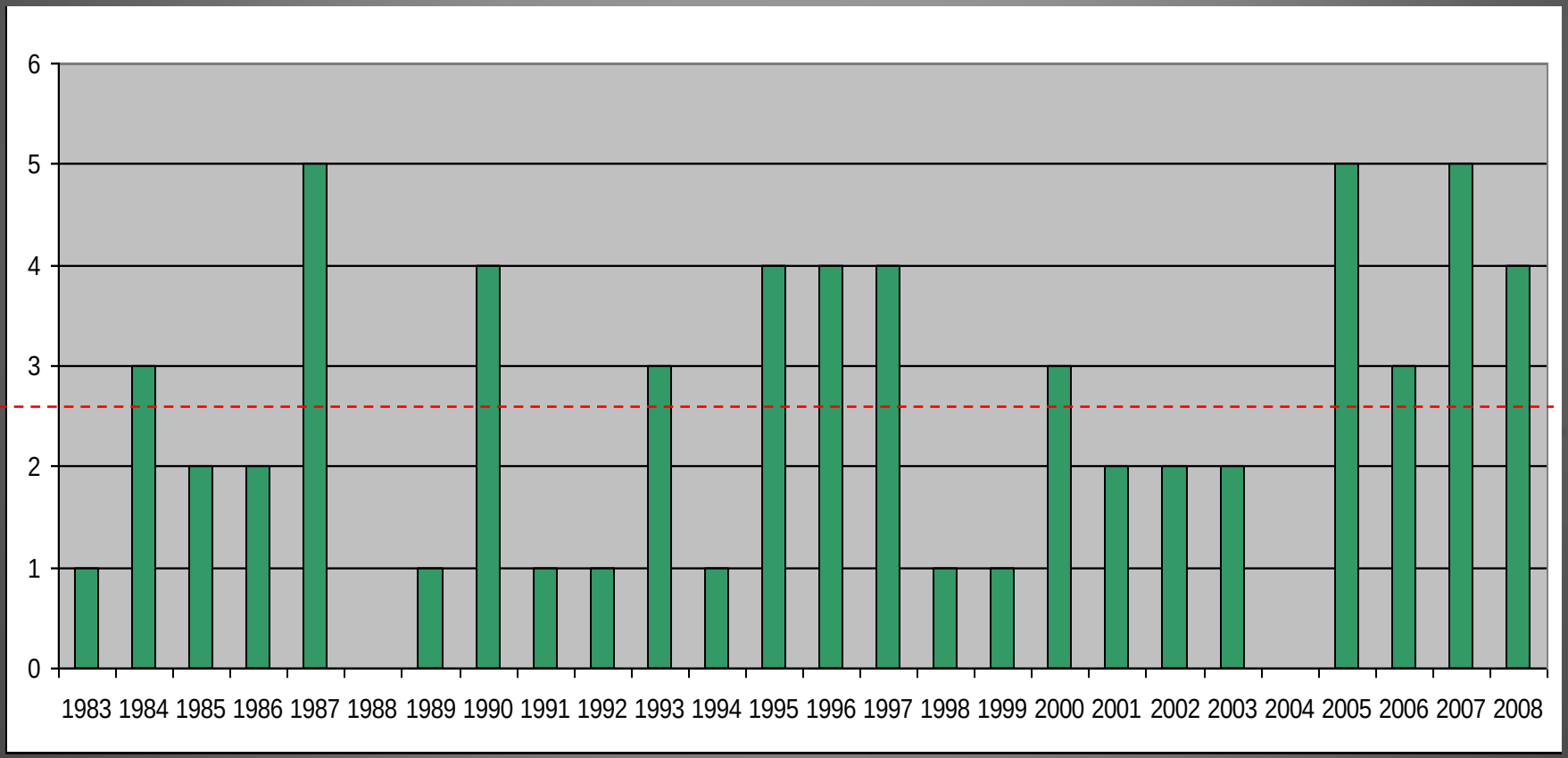
Source: Mammen, "Controlling the Plague…," 29 Berkeley Tech. L.J. 1329 (2009)

Federal Circuit Disposition of District Court Findings of IC



Source: Mammen, “Controlling the Plague…,” 29 Berkeley Tech. L.J. 1329 (2009)

Number of Cases Where CAFC Found Inequitable Conduct



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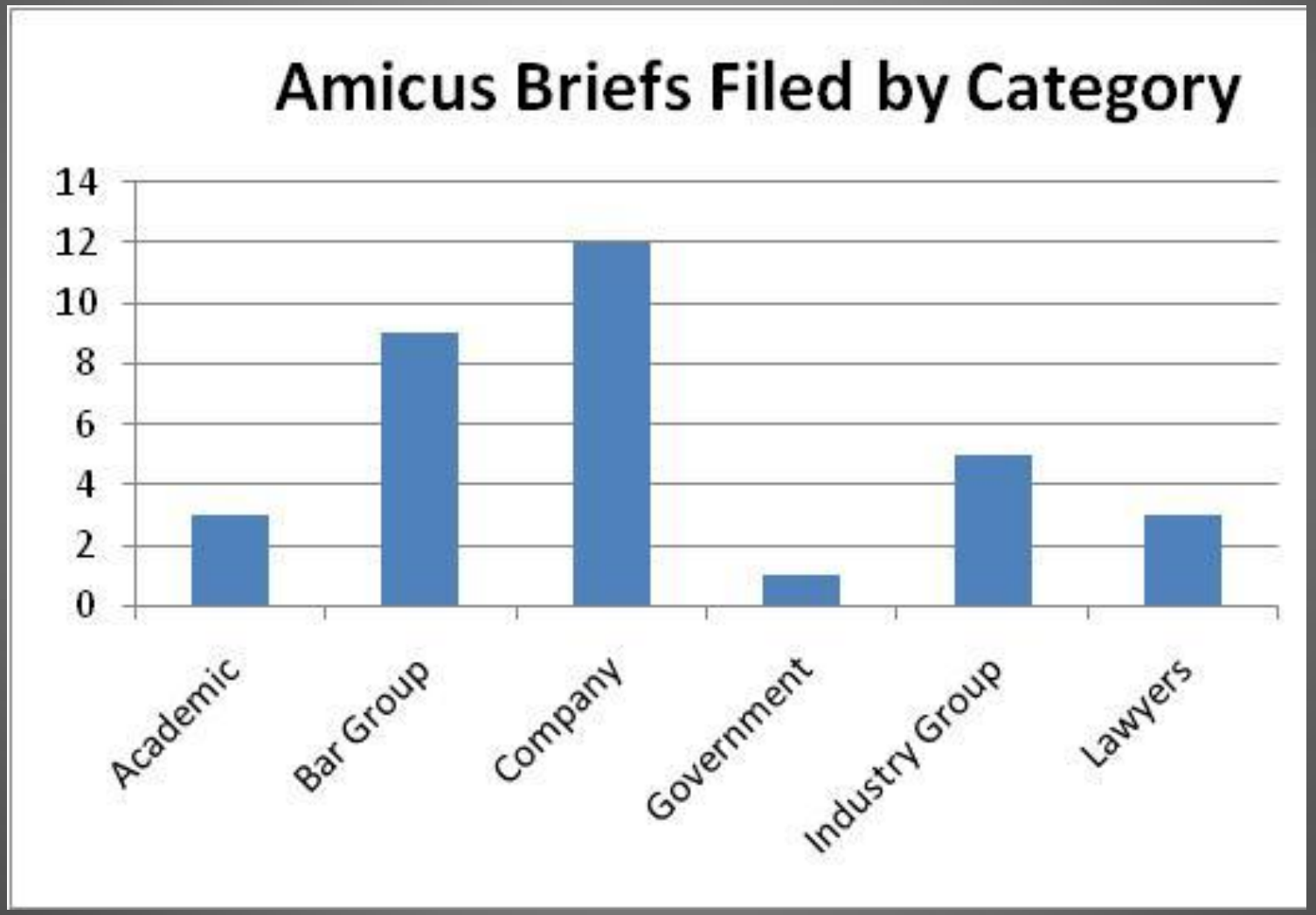
En Banc Rehearing

Therasense En Banc Questions

1. Should the materiality-intent-balancing framework for inequitable conduct be modified or replaced?
2. If so, how? In particular, should the standard be tied directly to fraud or unclean hands? … If so, what is the appropriate standard for fraud or unclean hands?
3. What is the proper standard for materiality? What role should [PTO rules] play in defining materiality? Should a finding of materiality require that but for the alleged misconduct, one or more claims would not have issued?
4. Under what circumstances is it proper to infer intent from materiality?
5. Should the balancing inquiry (balancing materiality and intent) be abandoned?
6. Whether the standards for materiality and intent in other federal agency contexts or at common law shed light on the appropriate standards to be applied in the patent context.

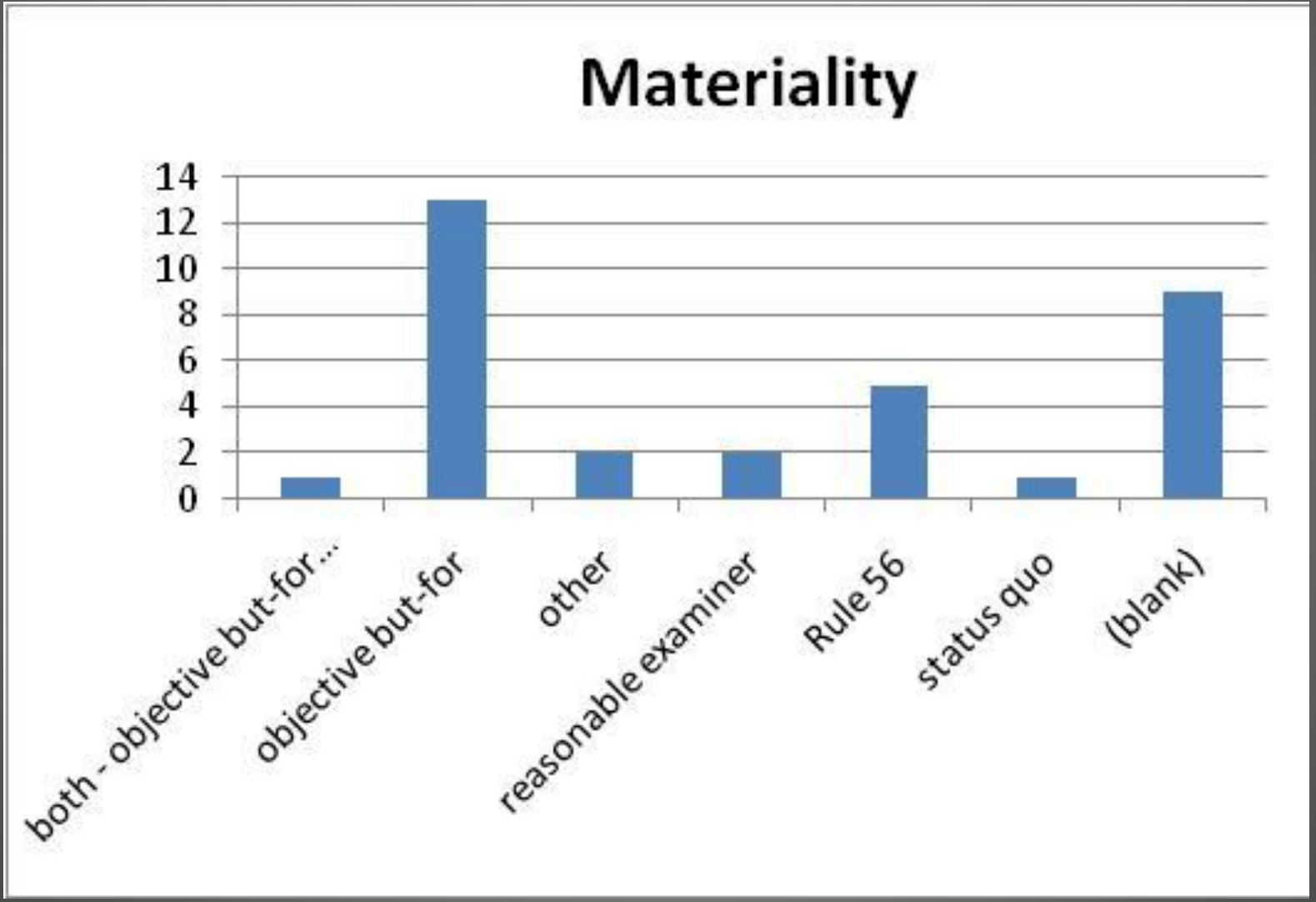
Amicus Briefs



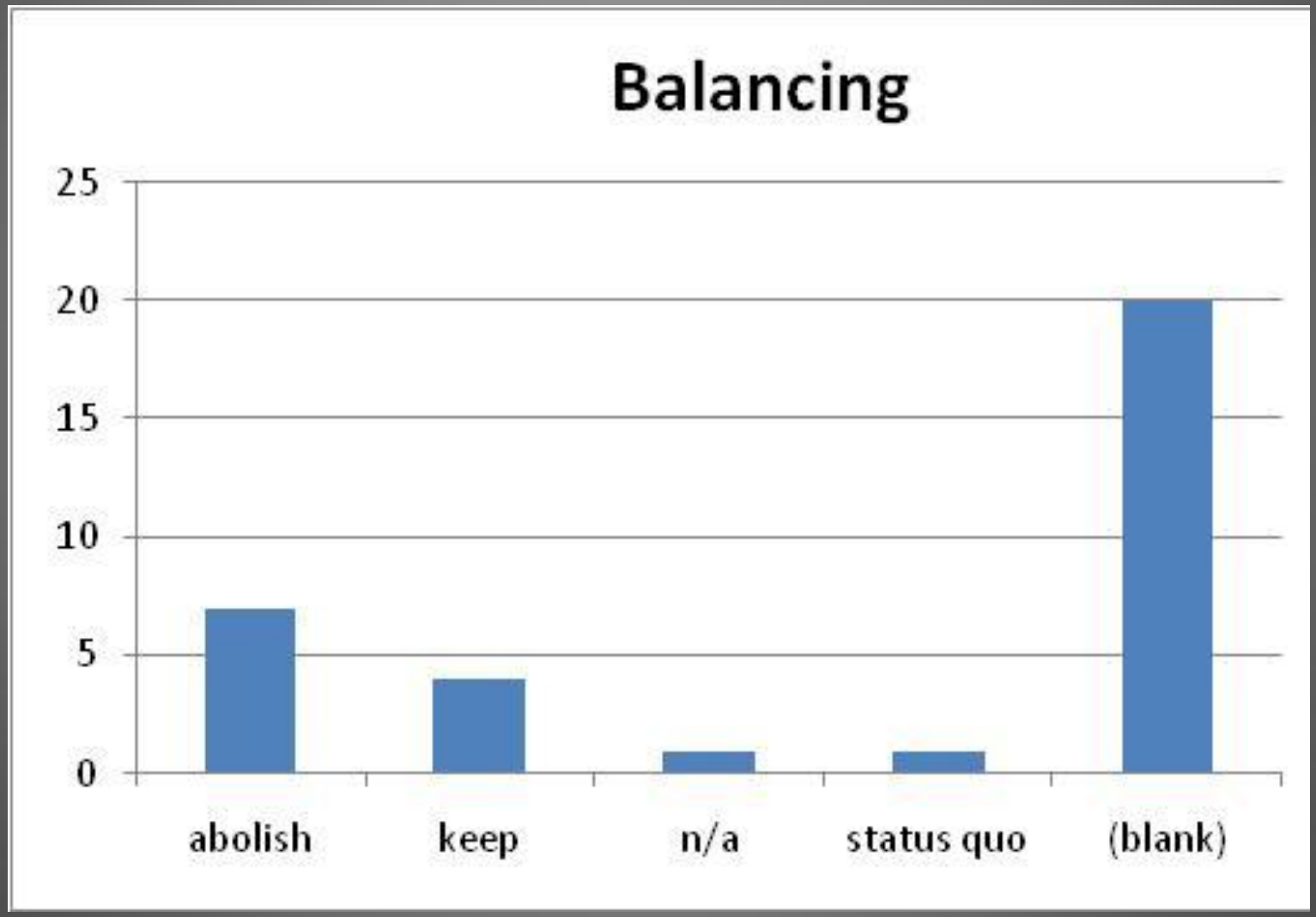
33 Amicus Briefs Filed

- Materiality
  - Most favor “but-for” test
  - Second choice is Rule 56
- Intent
  - Strong support for “specific intent”
  - Independence vs complete independence
  - Support for *Star Scientific* “single most reasonable inference” test
- Balancing
  - Slightly more favor abolition

Amicus Briefs

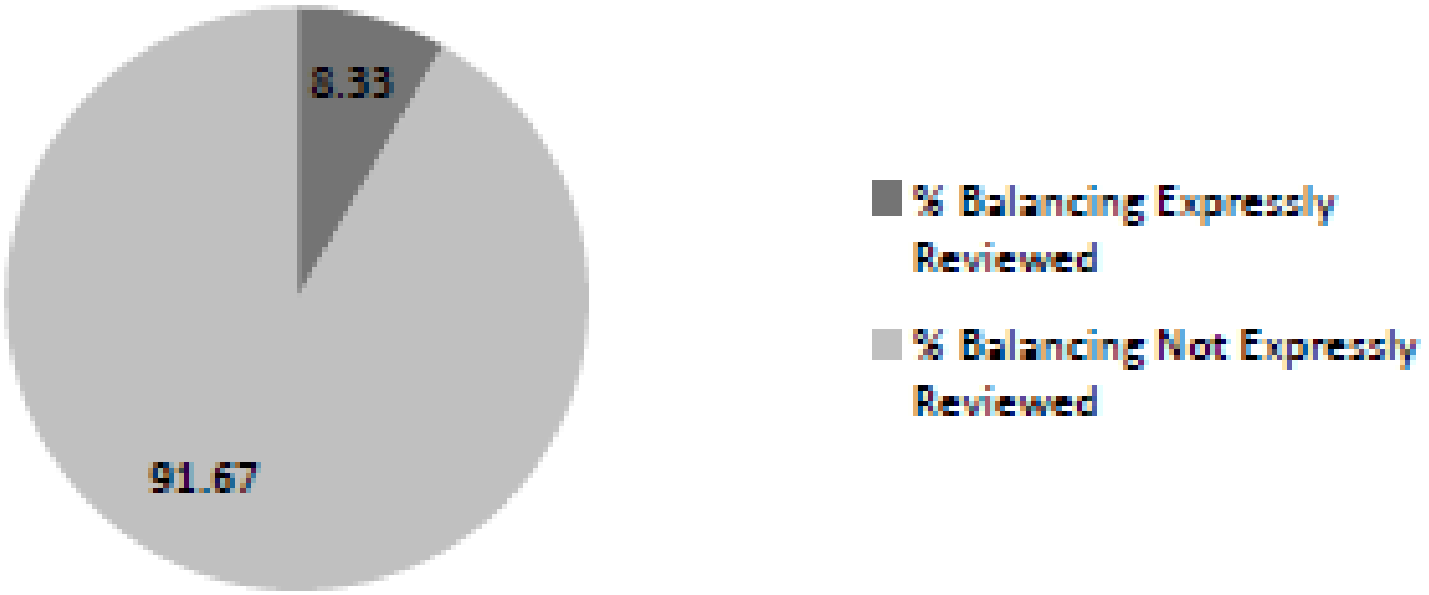


Amicus Briefs



Balancing is Insignificant

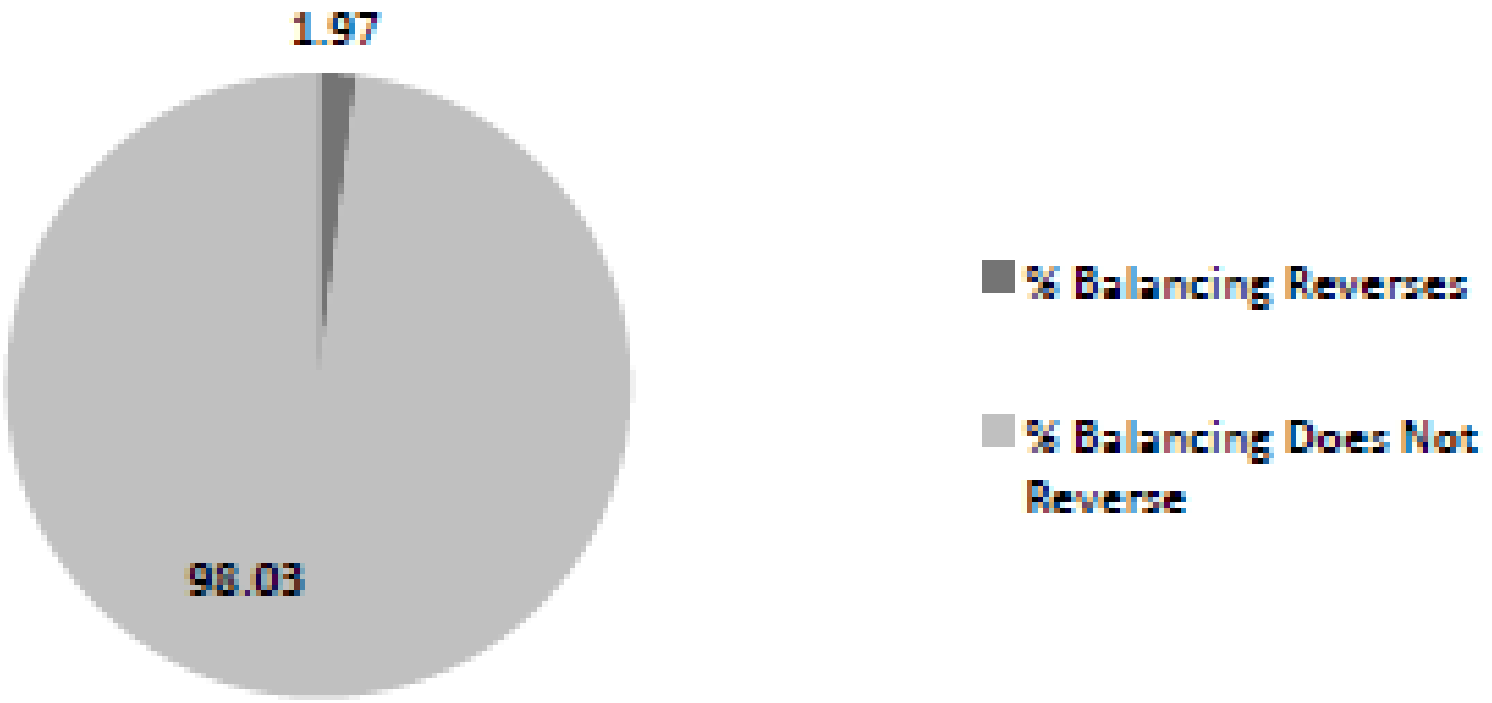
Figure 7. Rate at Which the Federal Circuit Expressly Reviews Equitable Balancing in Federal Circuit Written Inequitable Conduct Analyses (1983-2010) (n=361)



Source: Petherbridge, et al., "The Federal Circuit and Inequitable Conduct: An Empirical Assessment," (forthcoming 2011)

Balancing is Insignificant

Figure 8. Rate at Which Federal Circuit Use Equitable Balancing to Reverse a Lower Court Judgment that Inequitable Conduct Ocurred (1983-2010) (n=151)



Source: Petherbridge, et al., "The Federal Circuit and Inequitable Conduct: An Empirical Assessment," (forthcoming 2011)

Perspectives on Reform

Perspectives on Reform

- PTO
- Prosecution Counsel
- Litigation
  - Plaintiff-patentee
  - Defendant-accused infringer
  - Parties who play both roles over time
- Courts

Prosecution Counsel's Perspective

- Very limited role in litigation
  - Fact witness
  - Duties of loyalty, to protect privilege
  - No standing to intervene or challenge ruling

Prosecution Counsel's Perspective

- What doctrine would best serve prosecutors' compliance efforts?
  - Materiality
    - Bright-line rule
    - Criteria that are determinate at time of prosecution
  - Intent
    - Single most reasonable inference
    - Clear and convincing evidence of knowledge of –
      - Information
      - Materiality (and falsity)
      - Duty to disclose
    - Despite knowledge, made a deliberate decision to withhold

Litigation Counsel's Perspective

- While inequitable conduct may be frequently asserted, it is actually already very difficult to prove
  - Tried to judge not jury
    - Natural bias in favor of good faith of counsel
  - Standard of proof high
    - clear and convincing
  - Difficulties of proof after the fact
    - Intent is particularly difficult to demonstrate
    - A higher materiality standard would increase proof difficulties

Litigation Counsel's Perspective

- New, tougher pleading standards also makes litigating inequitable conduct more difficult
- In *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312 (Fed. Cir. 2009), the Federal Circuit held that inequitable conduct must be pled with particularity under FRCP 9(b), which governs the pleading of fraud
  - "we hold that in pleading inequitable conduct in patent cases, Rule 9(b) requires identification of the specific ***who, what, when, where and how*** of the material misrepresentation or omission committed before the PTO." *Id.* at 1327 (emphasis added).

Litigation Counsel's Perspective

- At this point, the level of detail required is often too high to meet at the answer stage
  - Indeed, many of the district court cases are applying *Exergen* in the context of motions to amend
    - This creates a double-hurdle for litigators
- For example, pleading must not only include the specific omission/misrepresentation and how it is material, but also the exact names of the person(s) committing the inequitable conduct

Litigation Counsel's Perspective

- There has been some variation in how district courts are applying *Exergen*
  - Although *Exergen* stated, as to the "what" requirement, that a pleading must identify the exact claims – and claim limitations – implicated, some courts have held that an identification of claims, along with some discussion of the omitted references, is sufficient
    - *See, e.g., Kinetic Concepts, Inc. v. Convatec Inc.*, No. 1:08CV00918, 2010 WL 1427592 (M.D.N.C. Apr. 8, 2010); *Braun Corp. v. Vantage Mobility Int'l, LLC*, No. 2:06-CV-50, 2010 WL 403749 (N.D. Ind. Jan. 271, 2010).

Litigation Counsel's Perspective

- It is also not clear if there is a distinct "why" requirement
  - "Why" is not one of the elements listed in *Exergen* in the discussion of the Federal Circuit's adoption of the Seventh Circuit's test for pleading fraud, although it is discussed later in the opinion
    - The pleading must explain "'why' the withheld information is material and not cumulative, and 'how' an examiner would have used this information in assessing the patentability of the claims." *Exergen*, 575 F.3d at 1329-30.

Litigation Counsel's Perspective

- How the "why" requirement has been handled:
  - "Why" considered to be imbedded in the "how" analysis. *E.g.*, *Johnson Outdoors, Inc. v. Navico, Inc.*, No. 2:10-CV-67, 2011 WL 798478 (M.D. Al. Mar. 2, 2011).
  - "Why" requirement a separate requirement. *E.g.*, *Advanced micro Devices v. Samsung Elec. Co.*, No. C 08-00986, 2010 WL 963920 (N.D. Cal. Mar. 16, 2010)
  - "Why" requirement ignored (at least explicitly). *E.g., McKechnie Vehicle Components, Inc.* v. *Lacks Indus. Inc.*, No. 09-cv-11594, 2010 WL 4643081 (E.D. Mich. Nov. 9, 2010)

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