

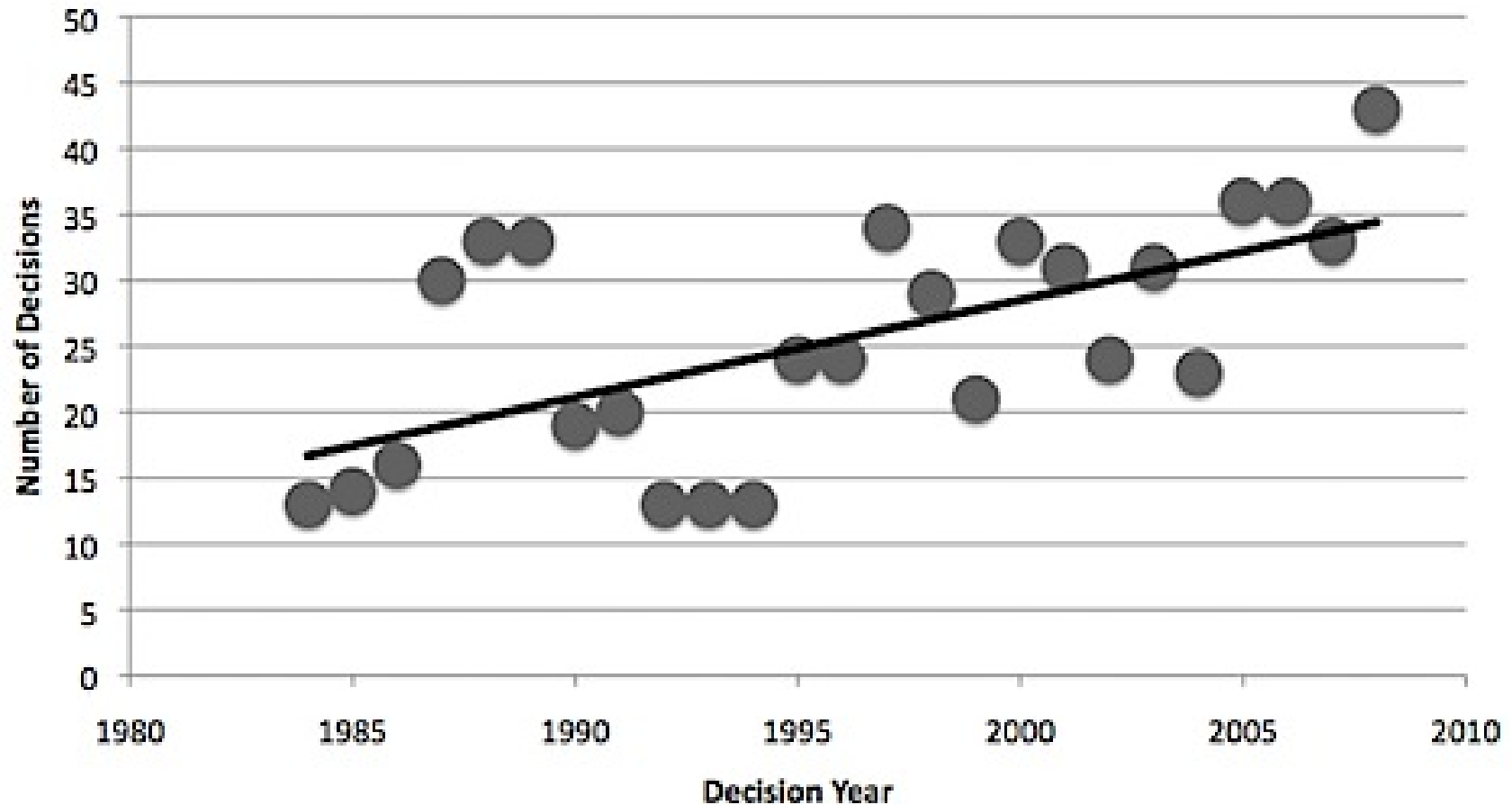
# Recent Trends in the Ethical Duty of Disclosure and Inequitable Conduct Law



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# Federal Circuit Decisions Discussing "Inequitable Conduct"



# Review – Elements of Inequitable

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Accused infringer must prove by clear and convincing evidence that the Applicant ...

**(1) MATERIALITY**

failed to disclose **material information**;

**AND**

**(2) INTENT**

... omitted above with **intent to deceive** the  
USPTO

**THEN**

**(3) JUDGE balances materiality and intent to decide  
on inequitable conduct**



# Review – Materiality Defined

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- Under 1992 USPTO Rule 56: Information is ***material*** when ...
  - it is ***not cumulative*** of information of record, **and**
  - (1) it establishes, by itself ***or in combination*** with other information, a prima facie case of unpatentability of a claim; **or**
  - (2) it refutes, or is inconsistent with, a position the applicant takes

# Review – Materiality Defined

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- Under Rule 56: Information is **material** when ...
  - it is **not cumulative** of information of record, and
    - (1) it is **not cumulative** of information of record, and
    - (2) it is **not cumulative** of information of record, and

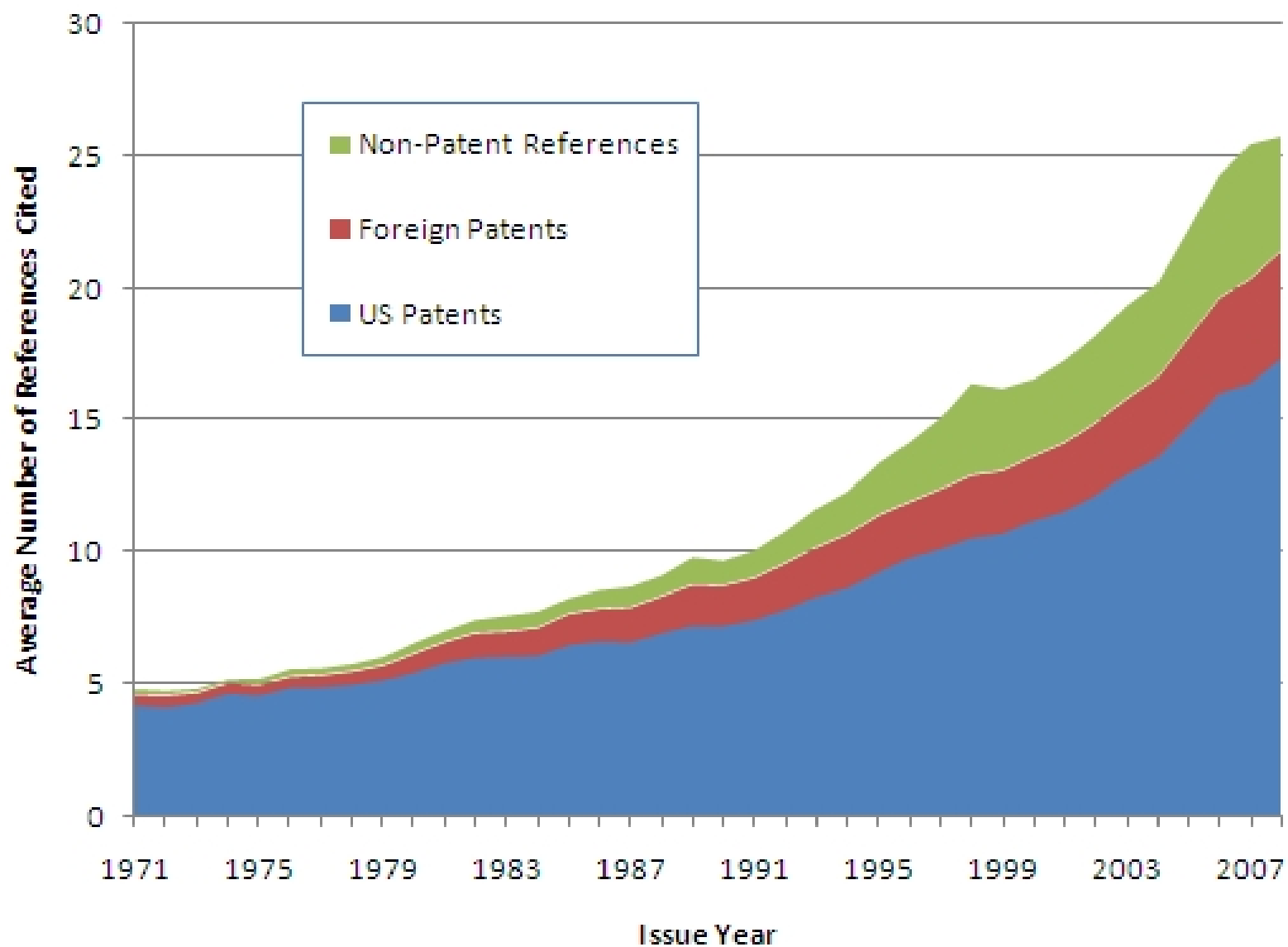
**NOT CUMULATIVE**

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The more information you disclose,  
the lower the risk of inequitable  
conduct

**Practical Tip**

**Disclose, disclose, disclose**

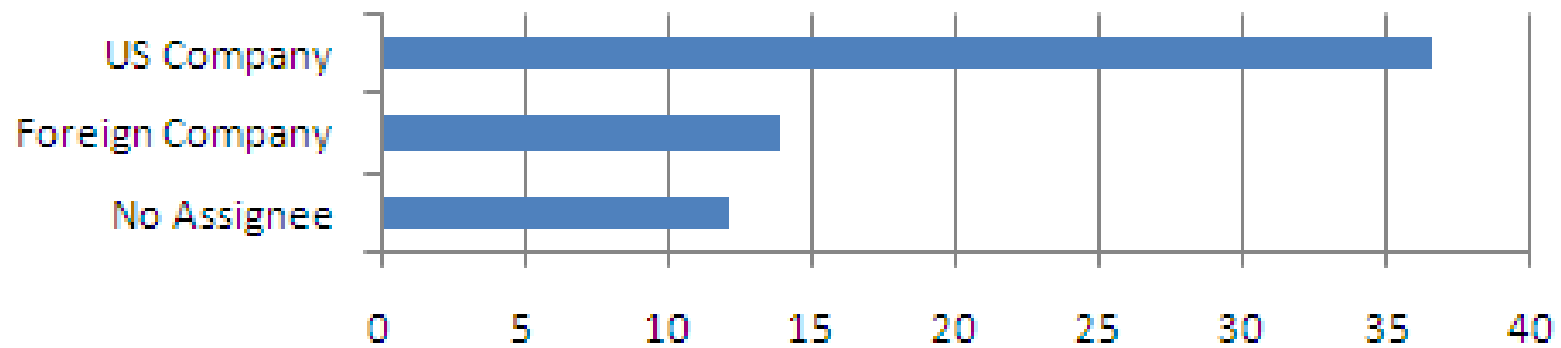


<http://www.patentlyo.com/patent/2008/09/information-dis.html>



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## Average Number of References Cited by Assignee According to Assignee Type



# Review – Materiality Defined (cont.)

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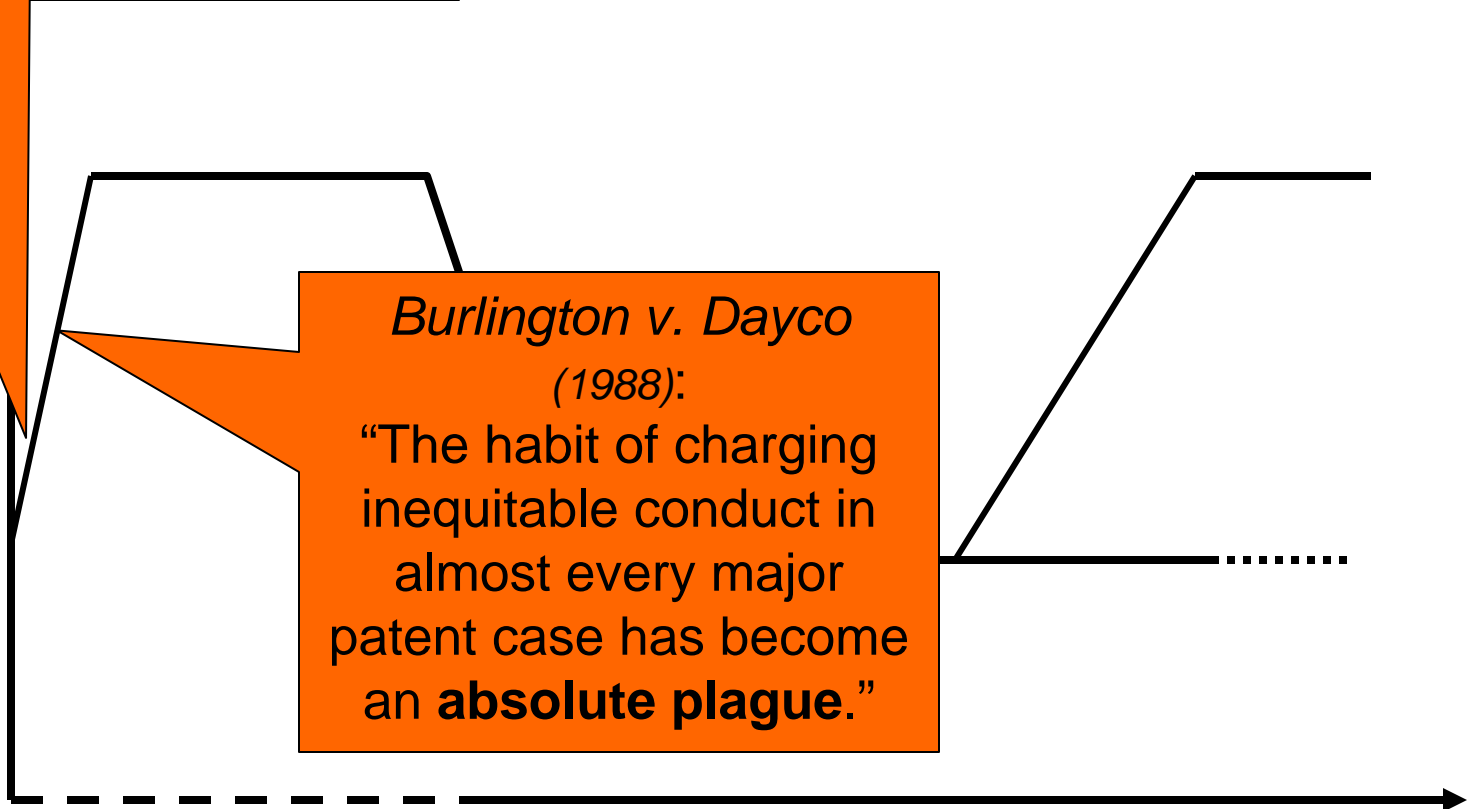
- “Old” (1977) USPTO Rule 56 still being applied *even for patents prosecuted after 1992!*:
  - Information can be material if a **reasonable examiner** would have considered such information **important** in deciding whether to allow the patent application.
    - *Digital Control v. Charles Machine Works* (Fed. Cir. 2006)
    - *Star Scientific v. R.J. Reynolds* (Fed. Cir. 2008)



# is difficult to define

Intent = applicant knew of the information + knew OR **should have known** of the materiality of the information

Evidence Required To show Intent



*Burlington v. Dayco (1988):*  
“The habit of charging inequitable conduct in almost every major patent case has become an **absolute plague.**”

1988

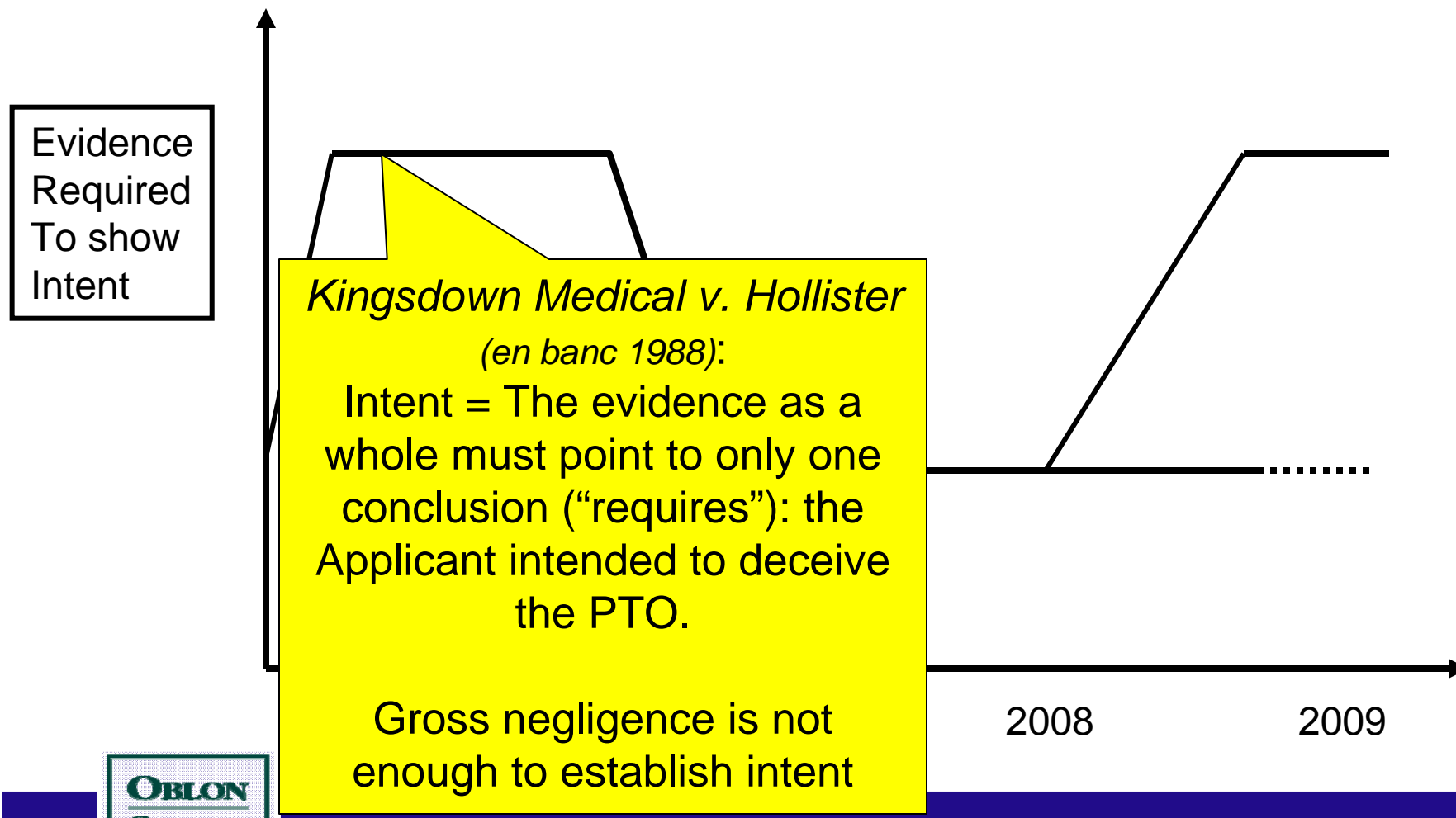
2006

2008

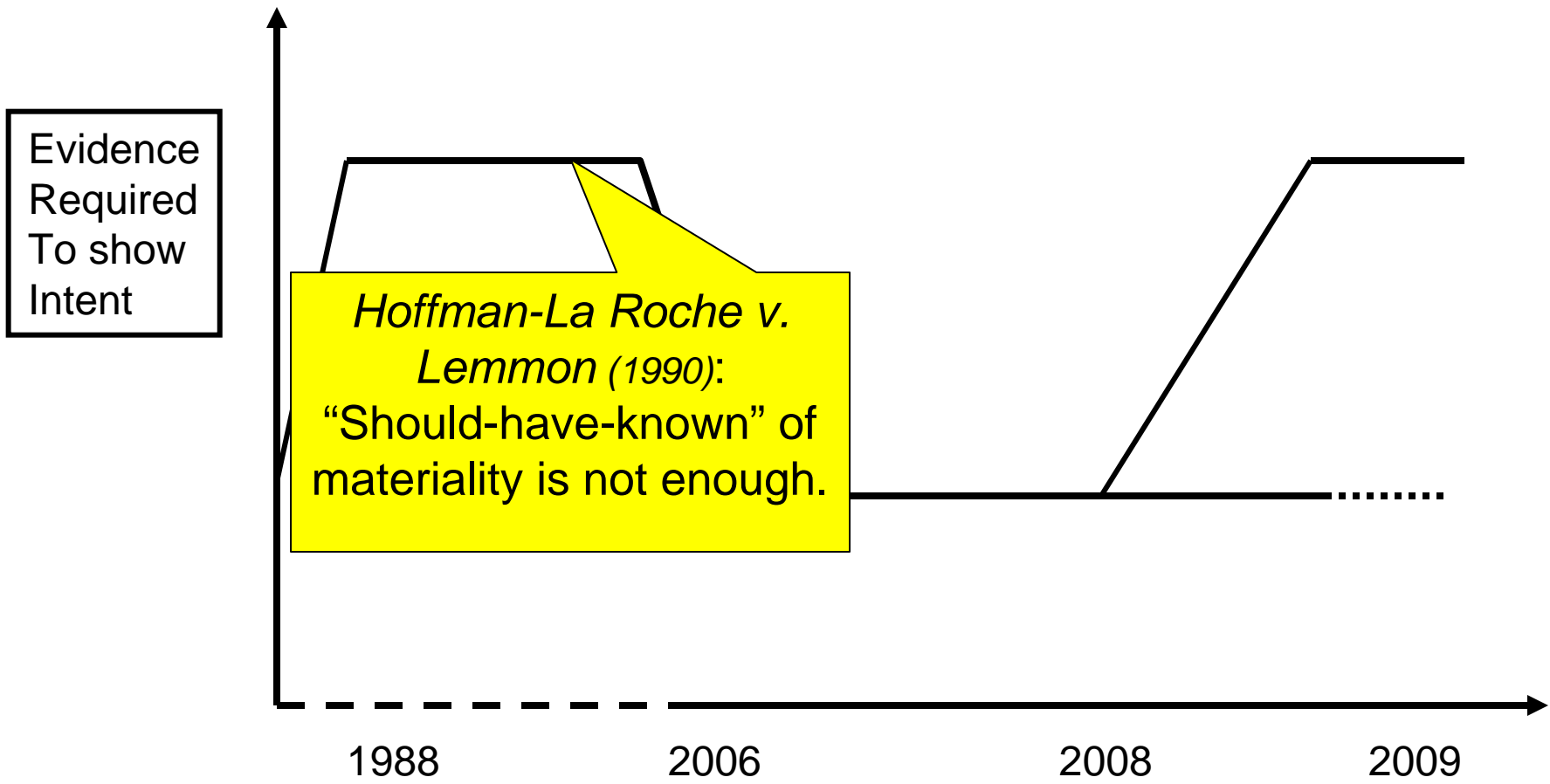
2009



# Intent: Always difficult to define



# Intent: Always difficult to define



***Critikon v. Becton Dickinson (1997)***

“A patentee facing a high level of materiality and clear proof that it knew or **should have known** of that materiality, can expect to find it difficult to establish subjective good faith sufficient to prevent the drawing of an inference of intent to mislead”

***Ferring v. Barr labs (2006):***

Intent = applicant knew of the information + knew OR **should have known** of the materiality of the information + no evidence of good faith (citing *Critikon*)

Judge Newman dissenting:  
Critikon is “bad law” in view of Kingsdown  
The plague is resurrected

1988

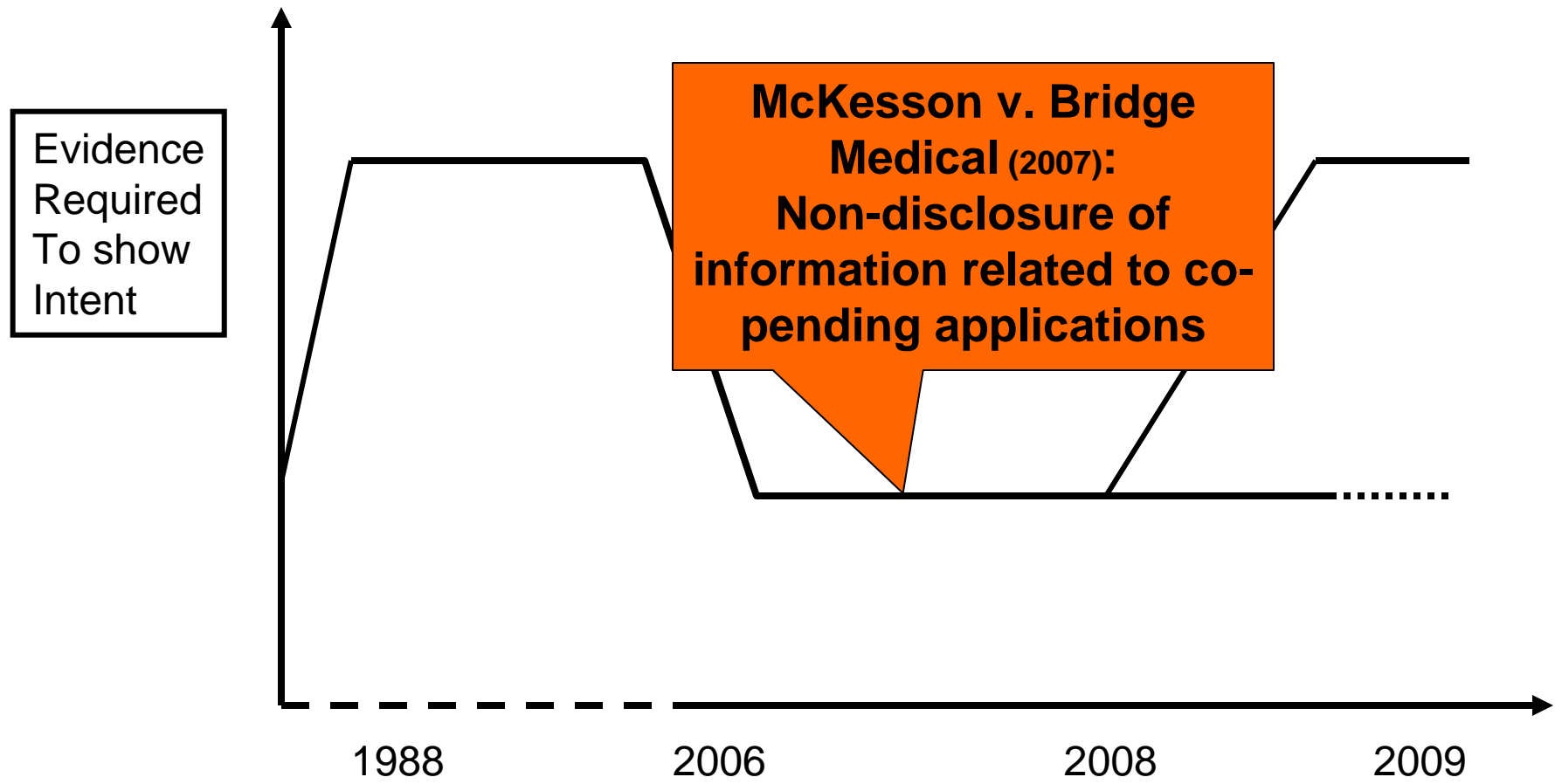
2006

2008

2009

# Intent: Always difficult to define

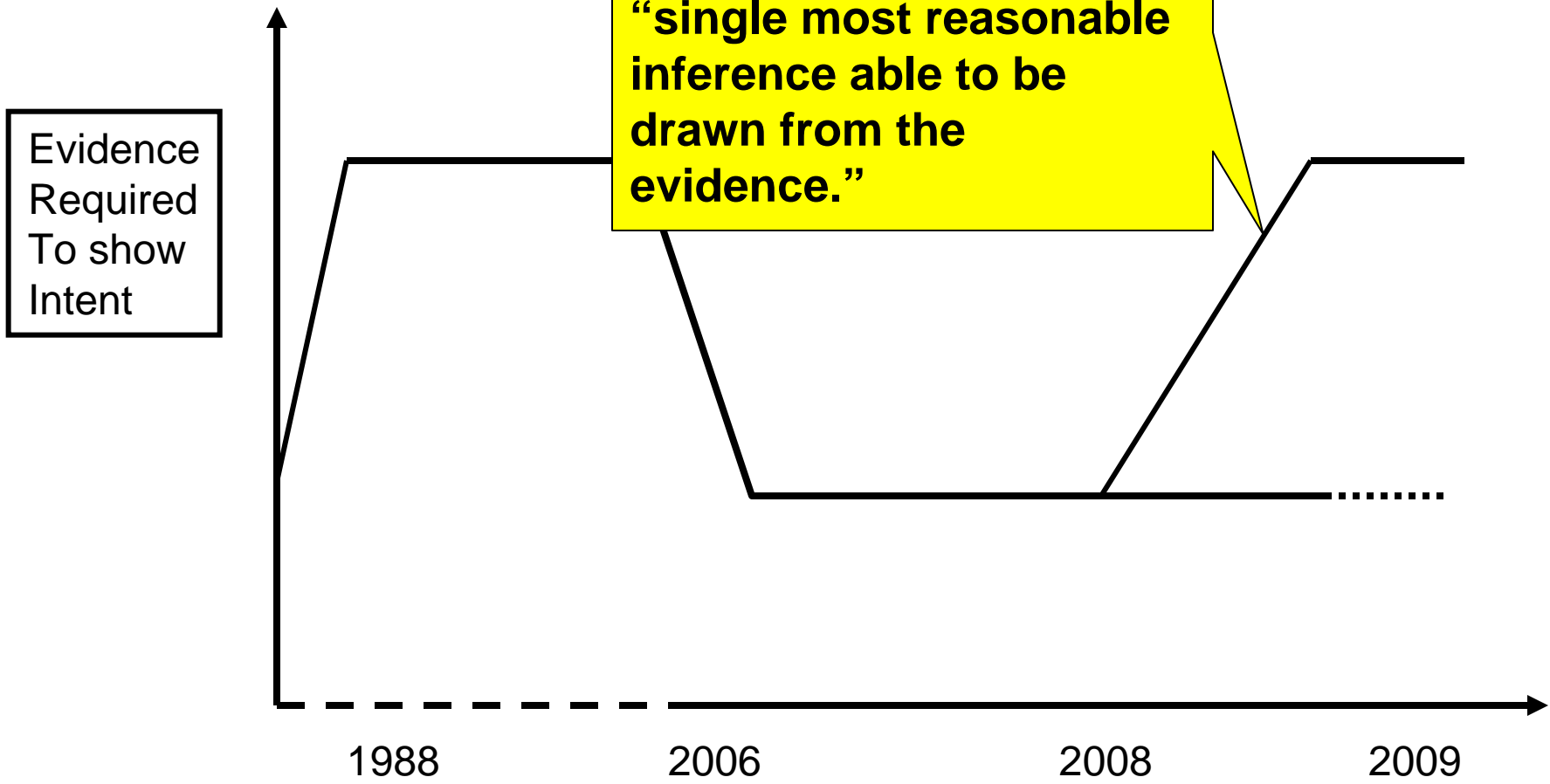
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# Intent: Always

# define

**Star Sci.v. R.J. Reynolds Tobacco (Aug. 2008):**  
“intent to deceive” =  
“**single most reasonable inference able to be drawn from the evidence.**”



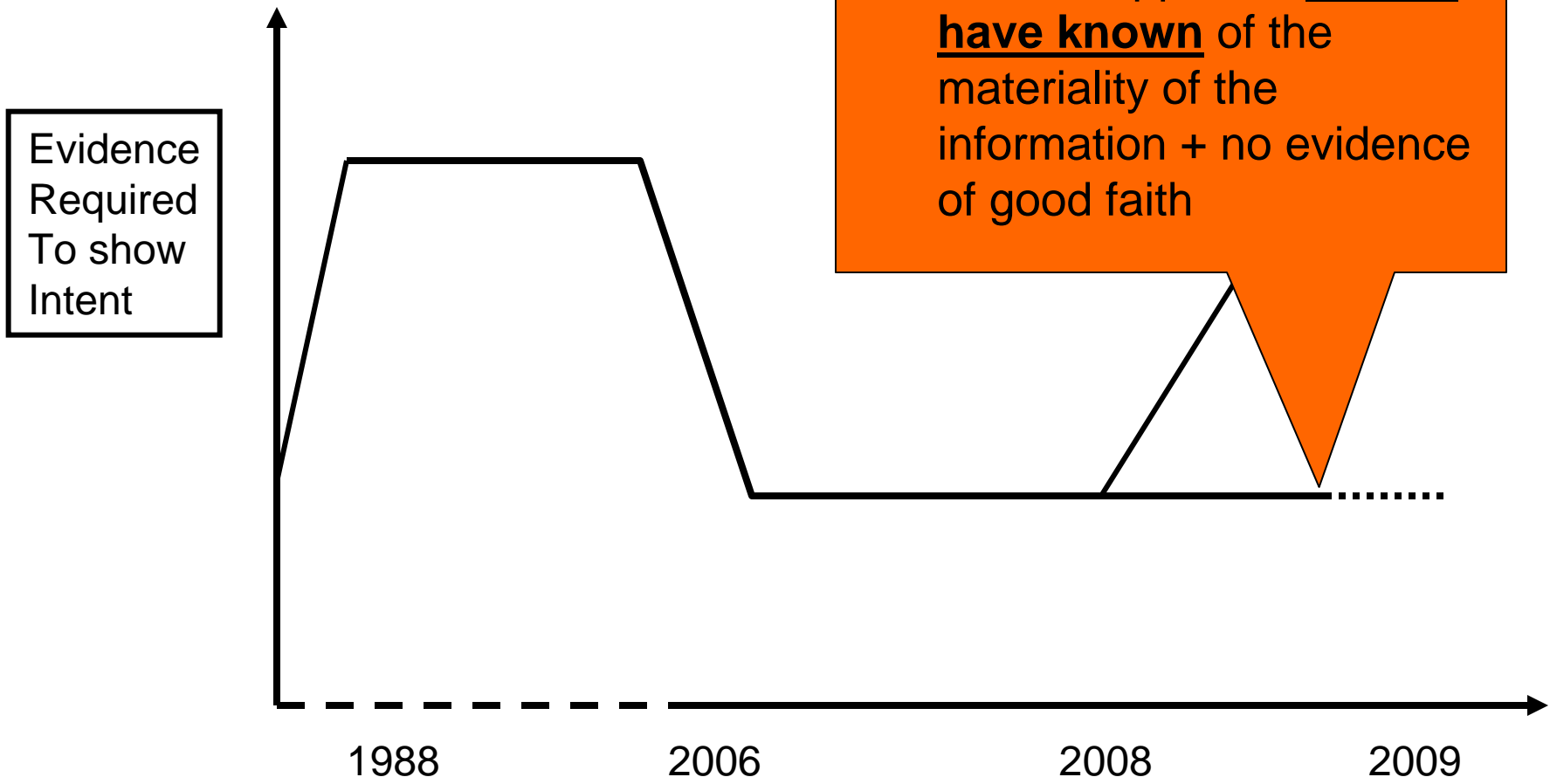
Evidence Required To show Intent



# Intent: Always dif

*Praxair, Inc. v. ATMI* (Sept 2008)

Intent = applicant **should have known** of the materiality of the information + no evidence of good faith

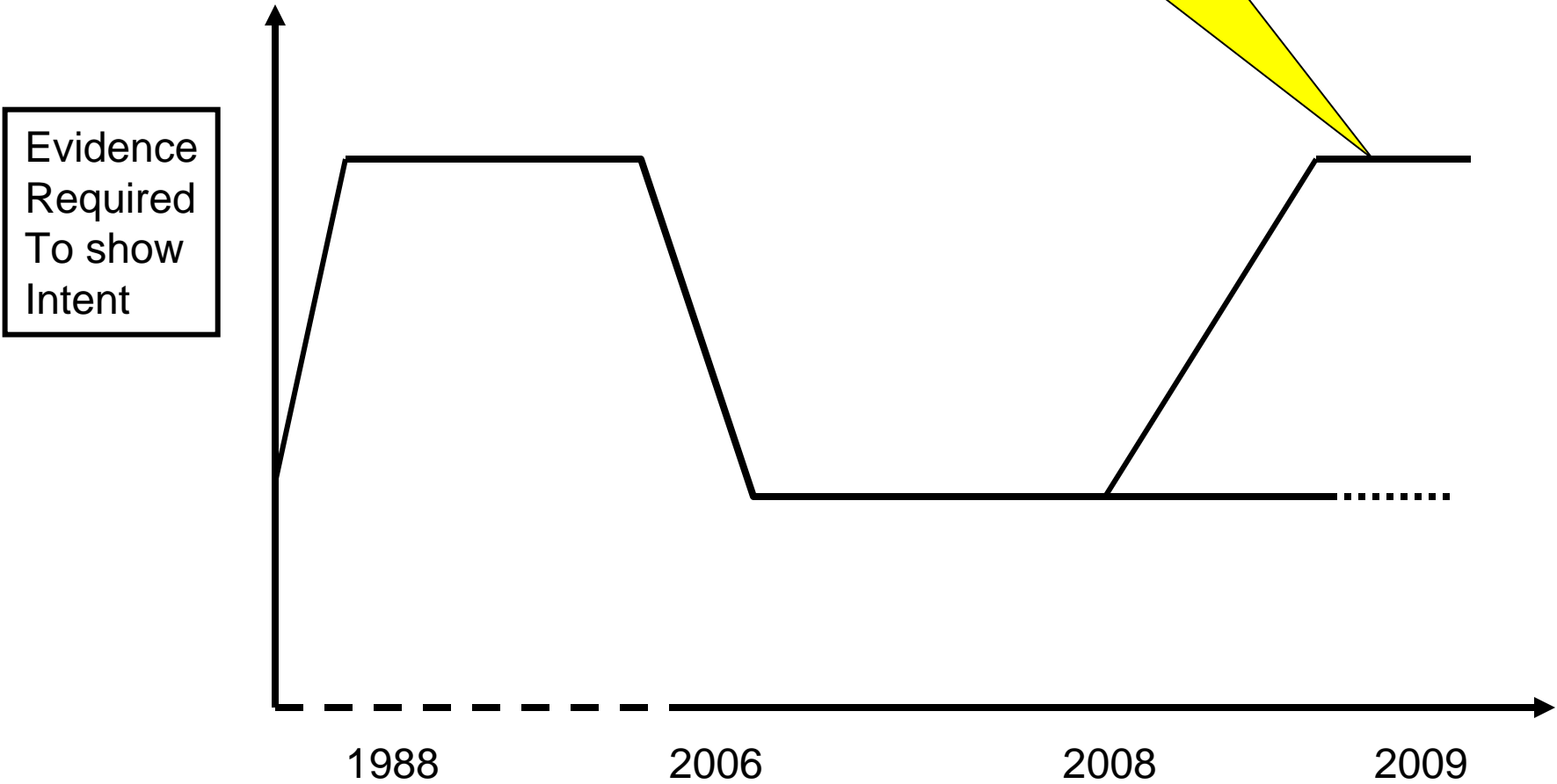


Evidence Required To show Intent



# Intent: Always difficult to define

Larson v. Aluminart (March 2009)



Evidence Required To show Intent



# Intent: Always different

***Ariad Pharma. Inc. v  
Eli Lilly  
(April 2009)***



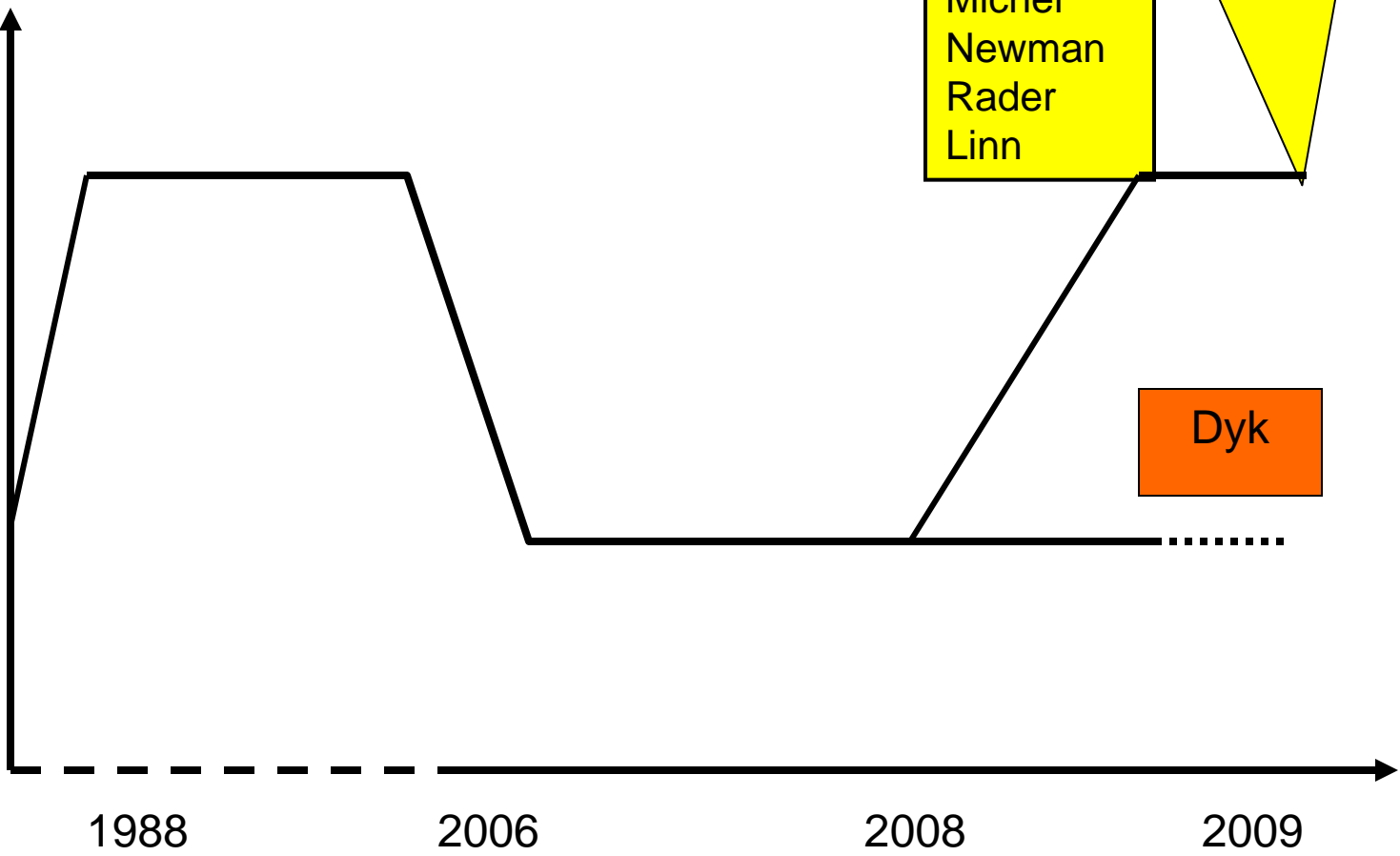
# Intent: Always difficult

Astrazenaca v Teva  
(Sept. 2009)

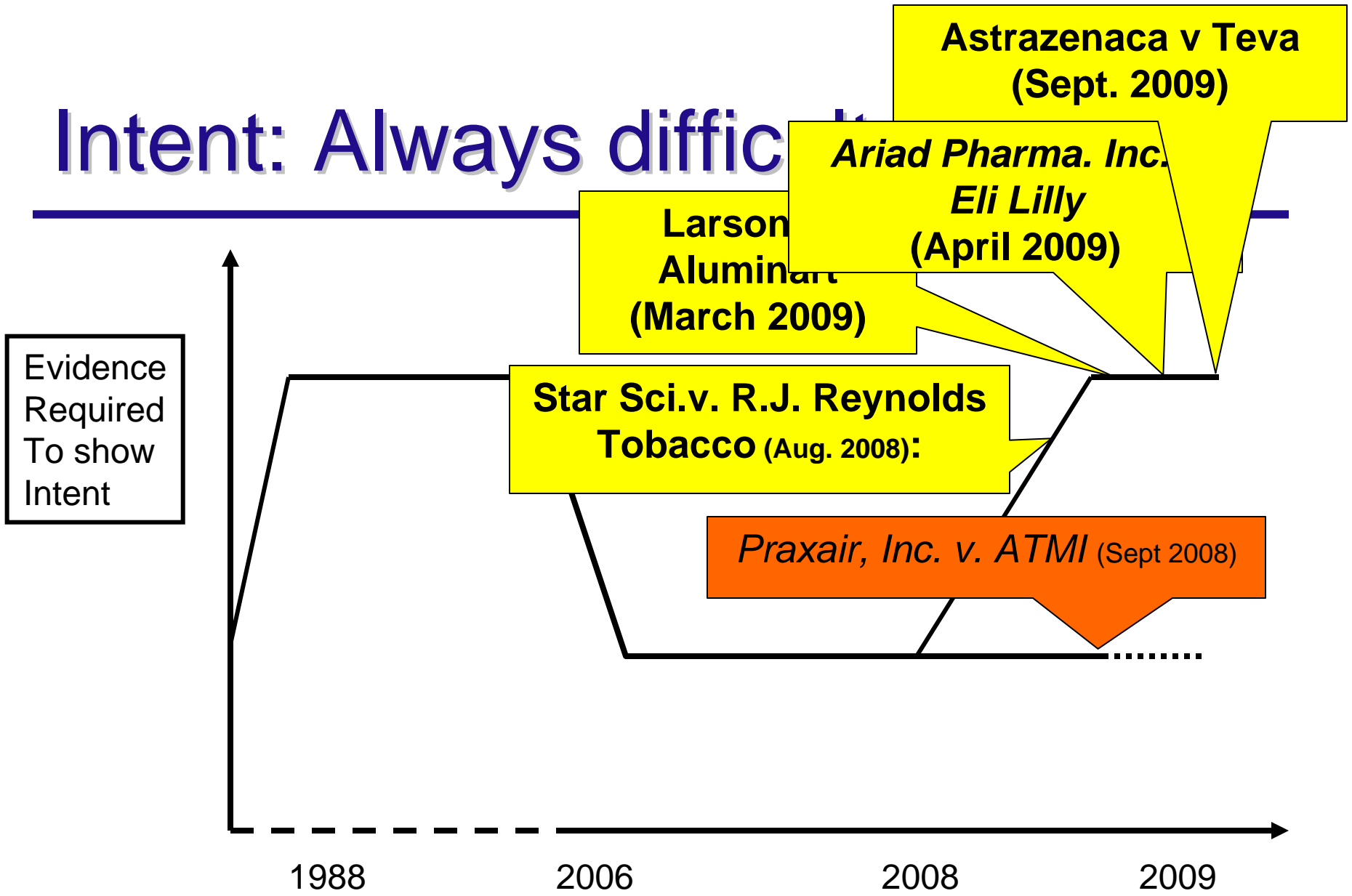
Michel  
Newman  
Rader  
Linn

Evidence  
Required  
To show  
Intent

Dyk

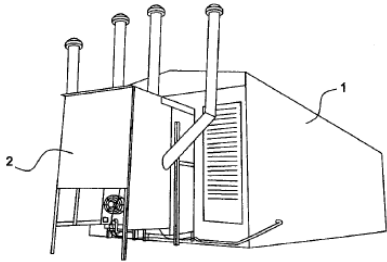


# Intent: Always difficult



Evidence  
Required  
To show  
Intent



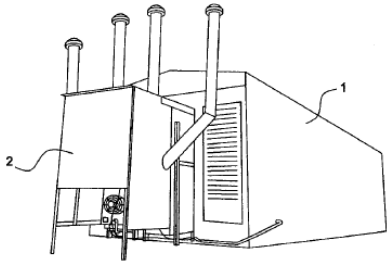


## Star Sci., Inc., v. R.J. Reynolds Tobacco Co.,

37 F.3d 1357 (Fed. Cir. Aug. 25, 2008) (Michel, C.J)

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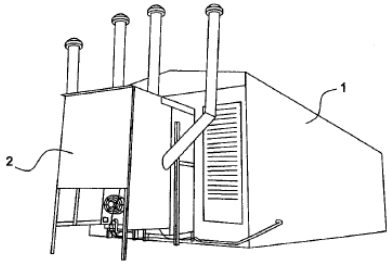
- Patents claimed method to cure tobacco that reduced carcinogens
- Consultant of applicant forwarded to prosecuting attorney prior art that disclosed a similar method to cure tobacco – but this prior art was not disclosed.
- Shortly after non-provisional application was filed, applicant switched prosecution firms, and had a third party handle the transition between firms
- Second law firm reviewed file for prior art, but apparently did not notice the consultant's letter. They filed an IDS without disclosing the letter, and a patent subsequently issued.



## Star Sci., Inc., v. R.J. Reynolds Tobacco Co.

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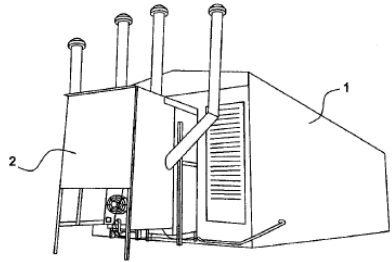
- The District court held that patentee intended to deceive the USPTO by switching law firms, such that the initial firm would not inform the later firm about the prior art and submit the prior art.
- Court did not believe patentee's explanation that they switched firms because a partner in the first firm died.



## Star Sci., Inc., v. R.J. Reynolds Tobacco Co.

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- Chief Judge Michel explains the significance of the “clear and convincing evidence standard,”
  - Historically intended to punish only most severe forms of intentional deception, i.e., outright fraud on PTO;
  - Indirectly criticizes the application of the Ferring standard.
- Fed. Cir. finds no clear and convincing evidence that deception was behind the switch of law firms;
  - No evidence that during prosecution, Patentee’s decision-makers or inventor knew of prior art,
  - Defendants had not even asked the Patentee’s decision-makers about the prior art.



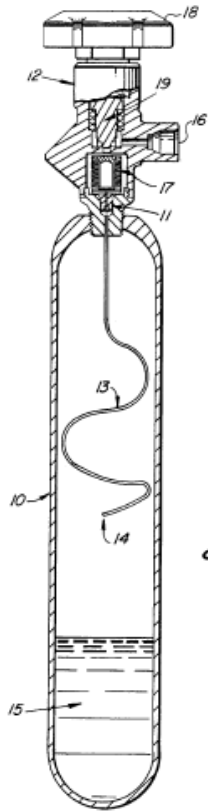
## Star Sci., Inc., v. R.J. Reynolds Tobacco Co.

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### Court Specifically Held:

- Patentee not required to offer a good faith explanation unless the defendant first meets burden to prove a threshold level of intent to deceive by clear and convincing evidence
- Clear and convincing evidence requires circumstantial evidence to be strong enough to point to “intent to deceive” as the “single most reasonable inference able to be drawn from the evidence.”

# Praxair, Inc. v. ATMI, Inc., 543 F.3d 1306 (Fed. Cir. Sept. 29, 2008) (Dyk, J.; Lourie, J., dissenting)



- '115 patent related to pressurized storage containers that limit accidental discharges of hazardous gases
- Applicants stated during prosecution that prior art did not provide (1) extreme flow limitation to prevent catastrophic discharge, or deliver toxic fluids from portable containers (2) simple safety measures, (3) or flow restrictions not exceeding 0.2mm.
- These statements were inconsistent with Applicant's admitted knowledge of prior art Restricted Flow Orifices (RFOs).
- RFO prior art defined highly material in view of applicant's statements



# Praxair, Inc. v. ATMI, Inc.

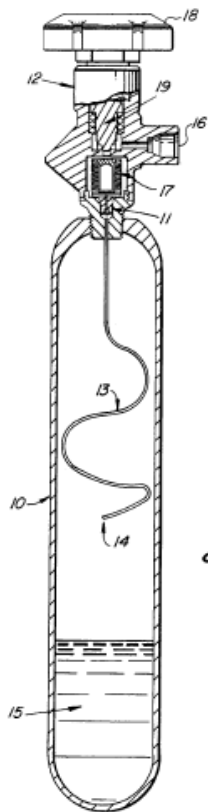


Fig. 1

## Star Scientific Decision did not end the Ferring Case

- One month after Star Scientific, Federal Circuit used *Ferring* test to infer intent to deceive and find inequitable conduct from (1) high materiality of prior art in view of statements characterizing the prior art during prosecution; (2) applicants knew of the prior art (actually, an entire class of RFO prior art) and (3) failed to provide a credible good faith explanation for non-disclosure
- Repeated Critikon's presumption, that with clear proof of (1) and (2) above, then applicant "can expect to find it difficult to establish 'subjective good faith' sufficient to prevent" a finding of intent.

# Praxair, Inc. v. ATMI, Inc.,

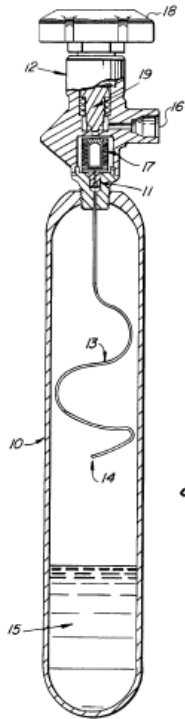
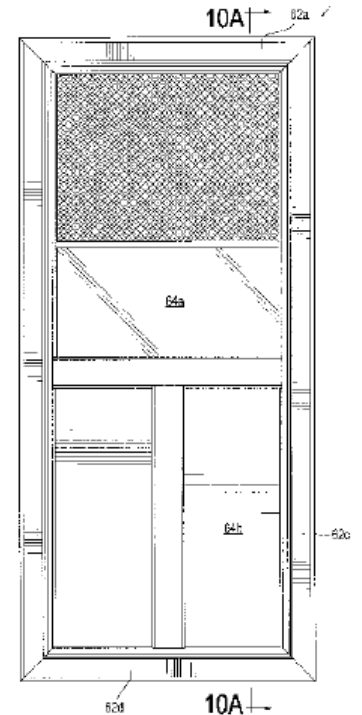


Fig. 1

- Star Scientific not mentioned
- Judge Lourie dissented, stating:
  - Inequitable conduct was based too much on materiality, and not sufficiently on intent;
  - No balancing of intent and materiality after establishing that both prongs meet threshold clear and convincing standard of proof;
  - Not even the Ferring test was properly followed, - “knew or should have known of the materiality” prong was not sufficiently addressed.

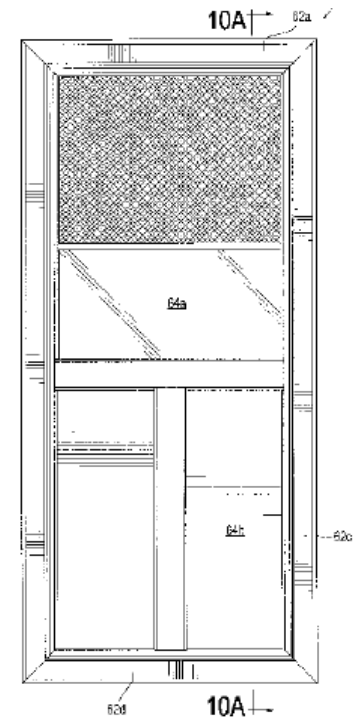
# Most Recent Cases Follow Higher Standard of Star Scientific

- **Larson Manufacturing v. Aluminart Products, Inc.**, 559 F.3d 1317 (Fed. Cir. March 18, 2009) (Schall)
- Fed. Cir. reverses-in part, and remands to district court for further findings on intent element, after finding three prior art references cumulative, and two office action material, which were not submitted during a reexam.
- District Court applied Ferring type test, which inferred intent based upon materiality of references, and lack of suitable excuse/explanation.



# Most Recent Cases Follow Higher Standard of Star Scientific

- **Larson Manufacturing v. Aluminart Products, Inc.**, 559 F.3d 1317 (Fed. Cir. March 18, 2009) (Schall) (cont.)
- Fed. Cir. provided guidance to district court on the intent element, citing heavily to Star Scientific and stating:
  - Materiality does not presume intent, and non-disclosure, by itself, cannot satisfy the deceptive intent element
  - While deceptive intent can be inferred from circumstantial evidence, it must still rise to the level of clear and convincing evidence
  - Larson need not provide a credible explanation if Aluminart has not first met its threshold showing of intent to deceive.
  - To meet clear and convincing standard, inference of intent to deceive must be the single most reasonable inference to be drawn from the evidence
- Judge Linn issued concurring decision directly attacking the Ferring-type cases (which includes Critikon), as contrary to Kingstown



**Ariad Pharmaceuticals Inc. v Eli Lilly**, 560 F.3d 1366 (Fed. Cir. April 3, 2009) (Moore) (Withdrawn for en banc rehearing on written description question)

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- In gene regulation case, patentee admitted materiality, and inequitable conduct case centered entirely on intent prong
- Fed. Cir. Affirmed district's court's finding of no inequitable conduct.
- Deceptive intent was not the single most reasonable inference to be drawn from Patentee's imperfect efforts to correct faulty figure in a family of applications. Efforts "signal an honest but imperfect attempts to correct mistakes."

## Ariad Pharmaceuticals Inc. v Eli Lilly (cont.)

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- No evidence of purposeful concealment of figure 43 no matter how material the error might be.
- Failure to submit four articles written by co-inventor that characterized other prior art was “plausibly” explained by co-inventor’s testimony that he did not wish to “inundate” the PTO with prior art, and deceptive intent was not a better explanation.
- Fed. Cir. Held that “absent a finding of deceptive intent, no amount of materiality gives the court discretion to find inequitable conduct.” (citing Star Scientific).

# **Astrazenaca Pharmaceuticals LP v Teva Pharmaceuticals USA, Inc. Case Nos. 2008-1480-1481 (Fed. Cir. September 25, 2009) (Newman)**

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- In pharmaceutical case, Fed. Cir. affirmed a district court's grant of summary judgment that a patentee did not commit inequitable conduct by failing to submit test data for less structurally similar compounds that exhibited claimed characteristics
- Fed. Cir. Disagreed with appellant's Ferring-type position that showing high materiality requires a lesser showing of intent to meet the threshold showing of intent to deceive
- Fed. Cir. Clarifies that the balancing of materiality and intent does not occur when determining the threshold level of intent
- Balancing only occurs as a final step, which "presupposes that a threshold level of both of these elements [intent and materiality] has already been established by clear and convincing evidence."

# New Heightened Pleading Requirement for Defense of Inequitable Conduct

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- **Exergen Corp. v. Wal-Mart Stores**, Case nos. 2006-1492, 2007-1180 (Fed. Cir. August 4, 2009) (Linn)
- Accused infringer moved to add inequitable conduct as an affirmative defense and counterclaim. The district court denied the request, holding that inequitable conduct is a form of fraud that must be pled "with particularity" under Fed. R. Civ. Pro. 9(b).
- Federal Circuit affirmed, stating that [T]o plead the 'circumstances' of inequitable conduct with the requisite 'particularity' under Rule 9(b), the pleading must identify the specific who, what, when, where, and how of the material misrepresentation or omission committed before the PTO.



# Accused Infringer's Fatally Defective Pleadings

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- DEFECT #1:
- [T]he pleading refers generally to “Exergen, its agents and/or attorneys,” Answer ¶¶ 40, 43, but fails to name the specific individual associated with the filing or prosecution of the application issuing as the '685 patent, who both knew of the material information and deliberately withheld or misrepresented it.

# Accused Infringer's Fatally Defective Pleadings

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- DEFECT #2:
- [T]he pleading fails to identify which claims, and which limitations in those claims, the withheld references are relevant to, and where in those references the material information is found—i.e., the “what” and “where” of the material omissions.

# Accused Infringer's Fatally Defective Pleadings

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- DEFECT #3:
- [T]he pleading states generally that the withheld references are “material” and “not cumulative to the information already of record,” Answer ¶¶ 41-42, but does not identify the particular claim limitations, or combination of claim limitations, that are supposedly absent from the information of record. Such allegations are necessary to explain both “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.

# Accused Infringer's Fatally Defective Pleadings

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- Moreover...pleading of inequitable conduct under Rule 9(b) must include sufficient allegations of facts to reasonably infer that a specific individual (1) knew of the withheld material information or of the falsity of the material representation, and (2) withheld or misrepresented this information with a specific intent to deceive the PTO.
- For omissions, facts must show that an individual with a duty to disclose, knew that a relevant reference existed,  
and
- also knew of the specific material information contained in that reference.

# Implications of Heightened Pleading Requirement

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- Much more difficult to assert inequitable conduct early in case as a counterclaim with defendant's answer to complaint
- Easier to dismiss any inequitable conduct claim that does not fully identify the individuals and allegations with sufficient specificity
- More likely to amend pleadings to add inequitable conduct counterclaims later in case, after some discovery conducted

# Conclusions

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- Federal Circuit seems unwilling or unable to rule on the intent element en banc. Requests for rehearing/en banc were denied in the Aventis, Star Scientific, Praxair, and the recent Larson v Aluminart case.
- Possible tension between:
- Pro-patent judges who wish to
  - permanently raise the bar for inequitable conduct
  - increase certainty and predictability in patent litigations
  - Consistent with its origin, apply inequitable conduct only in the most egregious cases

AND

- Judges who believe patent applicants will take advantage of the system unless the harsh punishments and a low bar for inequitable conduct is in place.



THANK YOU

