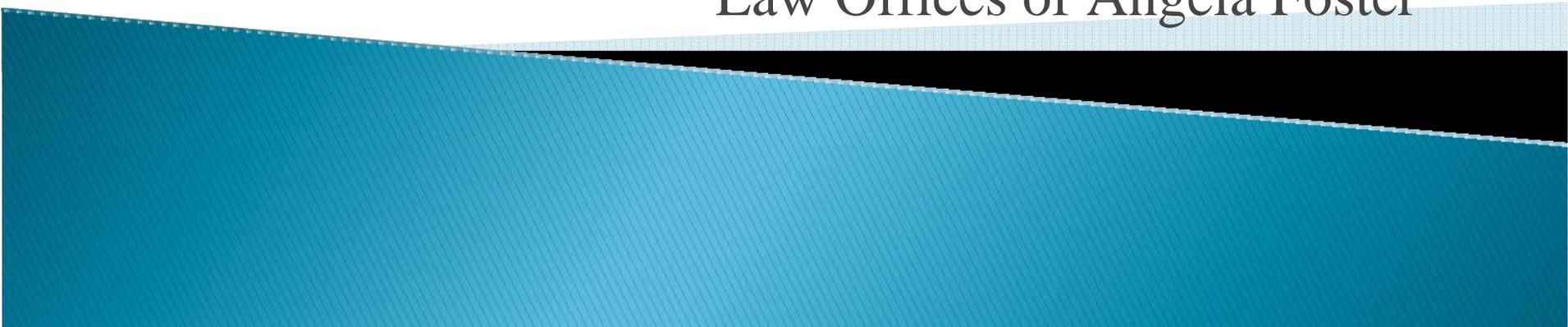
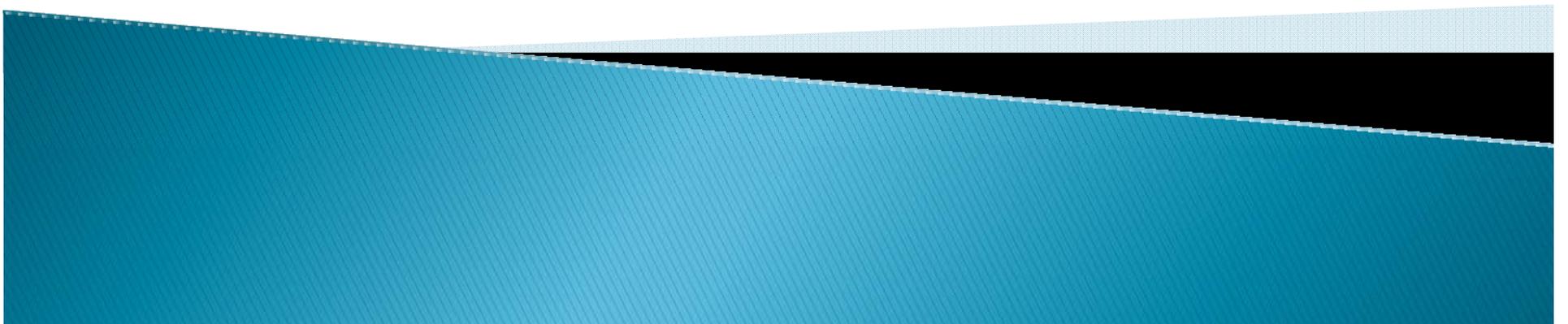


Ethical Considerations ***Post-Therasense* and** **Patent Reform Act**

Angela Foster, PhD, Esq.
Law Offices of Angela Foster

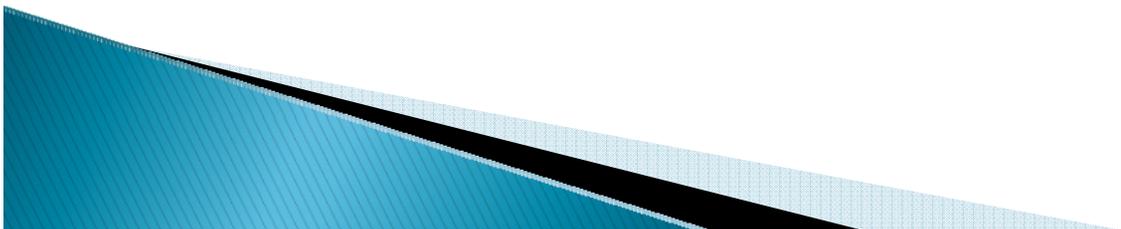


Inequitable Conduct



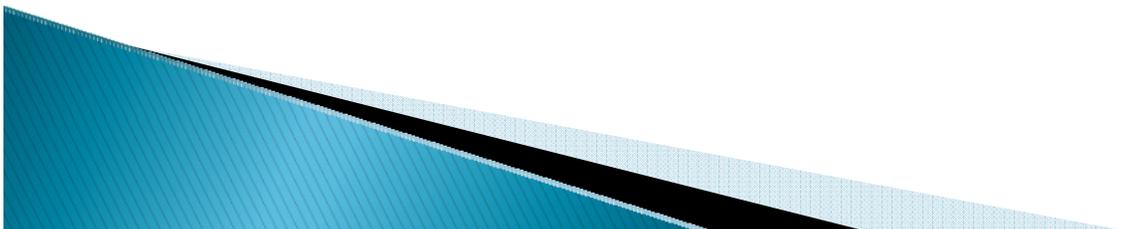
History of Inequitable Conduct

- ▶ Unclean hands
- ▶ Egregious Misconduct
 - Suppression of evidence:
 - Patentee paid a prior user to sign a false affidavit stating that his use was an abandoned experiment and bought his agreement to keep secret the details of the prior use and to suppress evidence. *Keystone Driller Co., v. Gen. Excavator, Co.*, 290 U.S. 240 (1933).
 - Manufacture of evidence:
 - Patentee's attorneys wrote an article describing the invention as a remarkable advance in the art and had a well-known expert sign and publish it. *Hazel-Atlas Glass Co. v. Hartford-Empire*, 322 U.S. 238 (1944).



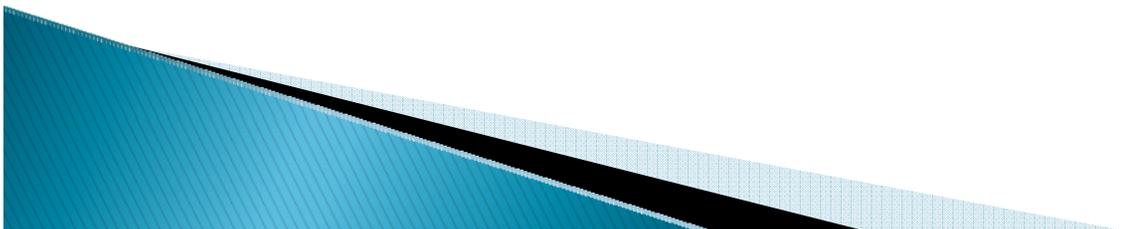
▶ **Results**

- Expansion of Inequitable Conduct Doctrine
 - Egregious affirmative acts of misconduct intended to deceive the PTO and the courts, and
 - Nondisclosure of information to the PTO.



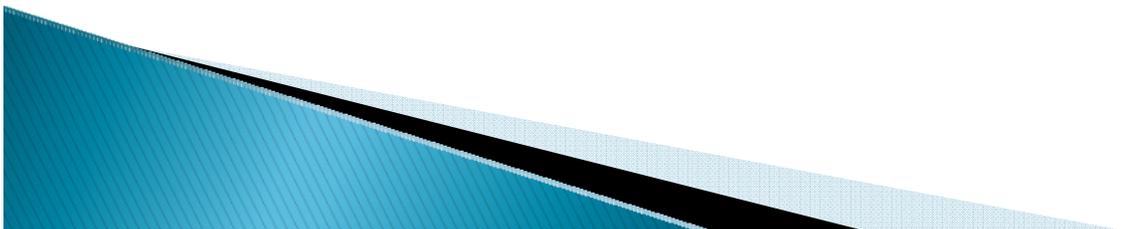
▶ **Gross Negligence Not Enough**

- *Kingsdown v. Hollister*, 863 F.2d 867 (Fed. Cir. 1988).
 - Prosecuting attorney incorrectly copied a rejected claim into the patent application which the PTO ultimately allowed as a patent.
 - The district court held the patent unenforce-able due to inequitable conduct because the attorney was grossly negligent in not noticing the mistake, or the attorney's actions were intended to deceive the PTO.
 - Sitting *en banc*, the Federal Circuit reversed and held a finding that a particular conduct amounts to gross negligence does not in of itself justify an inference of intent to deceive.



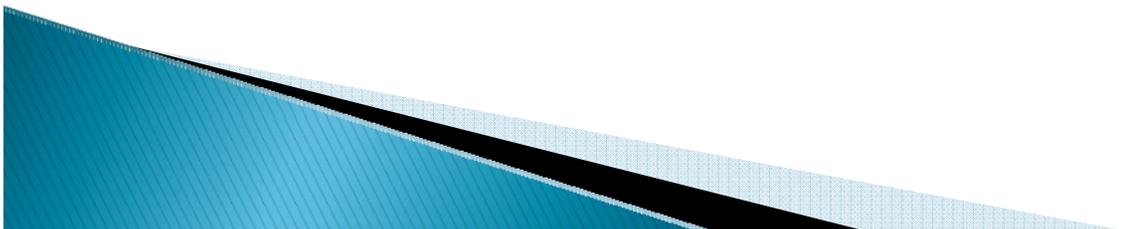
▶ Intent Inferred

- *Molins v. Textron*, 48 F.3d 1172 (Fed. Cir. 1995).
 - Attorney failed to disclose a relevant reference from counterpart foreign prosecution.
 - Reference was submitted to PTO among many references after patent was allowed.
 - Court found because the reference was so relevant, there must have been intent.
 - Court held that in a case involving nondisclosure of information, clear and convincing evidence must show that the applicant made a deliberate decision to withhold a known material reference.



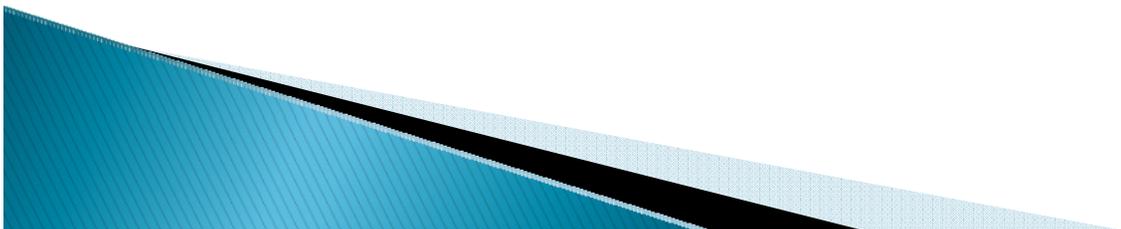
Rule --- Unenforceable Patent not just dismissal of lawsuit

A patent may be rendered unenforceable for inequitable conduct if an applicant, with intent to mislead or deceive the Examiner, fails to disclose material information or submits materially false information to the Patent Office during prosecution.



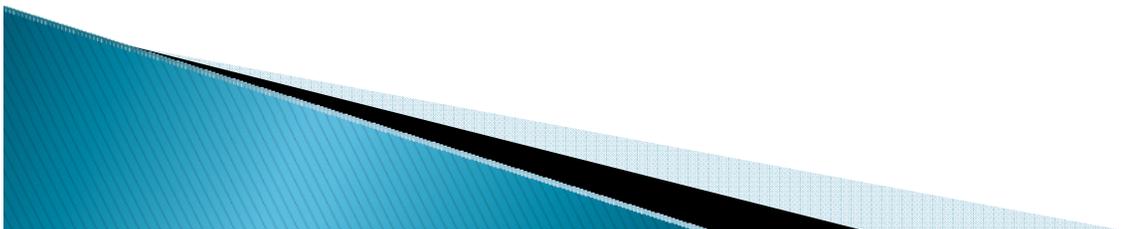
▶ Inequitable Conduct Defense

- To prevail on the defense of inequitable conduct, the accused infringer must prove that the applicant misrepresented or omitted material information with the specific intent to deceive the PTO.
- The accused infringer must prove **both** elements--intent and materiality--by clear and convincing evidence.
- If the accused infringer meets its burden, then the district court must weigh the equities to determine whether the applicant's conduct before the PTO warrants rendering the entire patent unenforceable.



Intent and Materiality are “Separate” Requirements

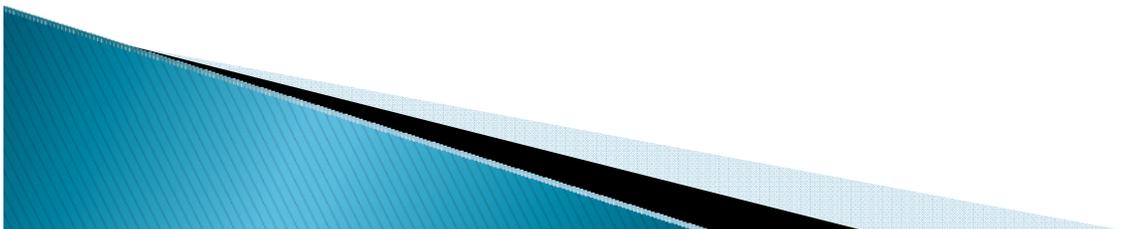
- A district court should not use a "sliding scale," where a weak showing of intent may be found sufficient based on a strong showing of materiality, and vice versa.
- A district court may not infer intent solely from materiality.
- A court must weigh the evidence of intent to deceive independent of its analysis of materiality.
- Proving that the applicant knew of a reference, should have known of its materiality, and decided not to submit it to the PTO does not prove specific intent to deceive.



Rule 56 - Duty to disclose information material to patentability

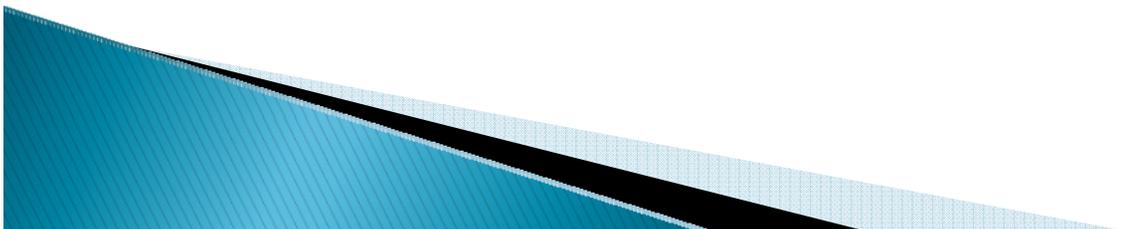
Information is material if:

- (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 in:
 - (i) Opposing an argument of unpatentability relied on by the Patent Office, or
 - (ii) Asserting an argument of patentability.



▶ **Ethical Responsibility – Sources of Information**

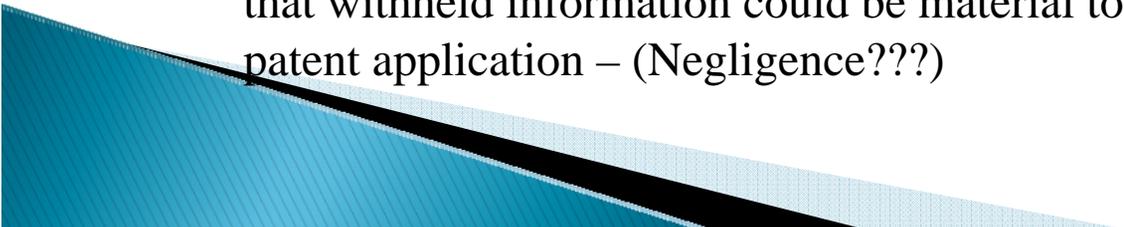
- Circumstances the information was obtained is irrelevant.
- If material, the information must be disclosed to the PTO.
- Duty to disclose includes material information that becomes known:
 - Prior to filing;
 - At the time of filing; and
 - During Prosecution.



Failure to Disclose - “Show have known”

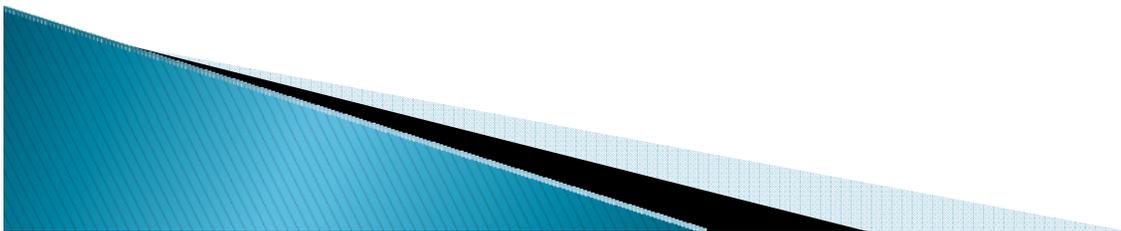
Bristol-Myers Squibb v. Rhone-Polenc Rorer

326 F.3d 1226 (Fed. Cir. 2003).

- Article was forwarded to Rhone-Polenc Rorer patent counsel regarding semi-synthesis of taxol that only certain hydroxyl-protecting groups worked.
 - The patent application claimed broad synthesis and failed to denote any limitation on the hydroxyl-protecting groups.
 - Failed to cite published article during prosecution.
 - Materiality is not limited to prior art, but includes any information a reasonable patent examiner would be substantially likely to consider important in deciding to issue a patent.
 - Intent may be inferred when a patent applicant knew, or should have known, that withheld information could be material to the PTO's consideration of the patent application – (Negligence???)
- 

Reasonable Examiner Standard

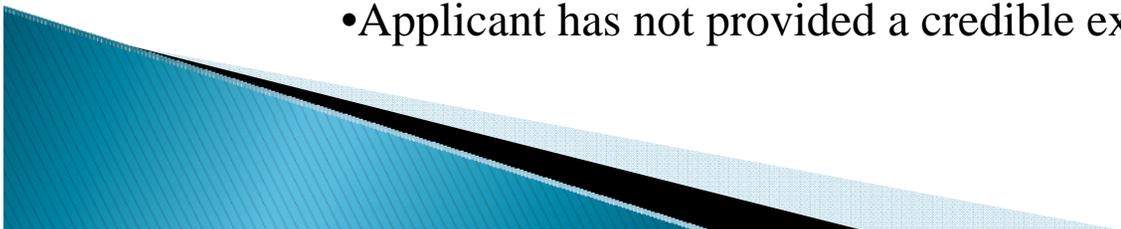
Any information that a reasonable examiner would substantially likely consider important in deciding whether to allow an application to issue as a patent.



Reasonable Examiner Standard

Ferring B.V. v. Barr Labs., Inc.,
437 F.3d 1181 (Fed. Cir. 2006).

- Invention concerned anti-diuretic drug used to treat diabetes.
- Prior rejections stated the prior art taught oral administration.
- Examiner requested submission from a non-inventor declaration.
- Patentee did not disclose that four of the five declarations submitted were written by scientists having a connection with the assignee.
- Court held:
 - Applicant knew the undisclosed information;
 - Applicant knew or should have known of the materiality of the information; and
 - Applicant has not provided a credible explanation for the non-disclosure.

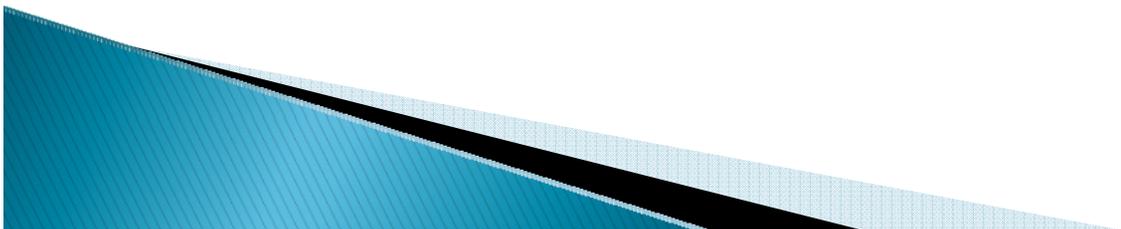


Expansion of the Scope of Materiality

McKesson Information Solutions v. Bridge Medical, Inc.

487 F.3d 897 (Fed. Cir 2007).

- Inequitable claims were based on non-disclosure of prior art.
- Rejection and references were cited co-pending application.
- Materiality
 - In co-pending claims a showing of substantial similarity is sufficient to prove materiality.
 - Materiality encompasses anything that would have been considered important by a reasonable examiner.
- Intent to Deceive
 - Can be inferred when the reference or action is highly material.



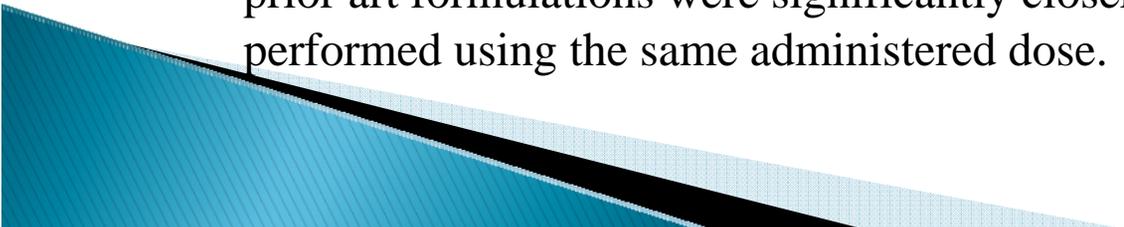
Inference of Intent

Cargill Incorp. v. Canbra Foods Ltd.,
476 F.3d 1359 (Fed. Cir. 2007)

- Cargill failed to disclose reports and data regarding the claimed chemical process.
 - Intent to deceive was denoted from the repeated nature of the omission, the applicant's motive to conceal, and the high materiality of the undisclosed information.
 - There were multiple occasions that called for disclosure of the omitted data.
 - The district court held:
 - "intent may be inferred where a patent applicant knew, or should have known, that withheld information would be material to the PTO's consideration of the patent application."
 - An applicant should know information is material when the examiner repeatedly raises an issue to which the information relates.
- 

Materiality & evidence of Intent to Deceive

Aventis Pharma v. Amphastar Pharmaceuticals, Inc.,
525 F.3d 1334 (Fed. Cir. 2008)

- Aventis expert submitted a declaration comparing the prior art and compounds of the claimed invention regarding mixtures of low molecular weight heparins used to prevent blood clotting.
 - Aventis submitted declarations containing data from various clinical studies comparing the half-life of their product with the half-life of the prior art product.
 - Aventis expert failed to disclose that the claimed formulations were administered at a different and higher dosage than the prior art compounds.
 - Aventis expert also failed to point out that the half-lives of the invention and prior art formulations were significantly closer when the comparison was performed using the same administered dose.
- 

Weight of Proof

Star Scientific Inc. v. R.J. Reynolds Tobacco Co.

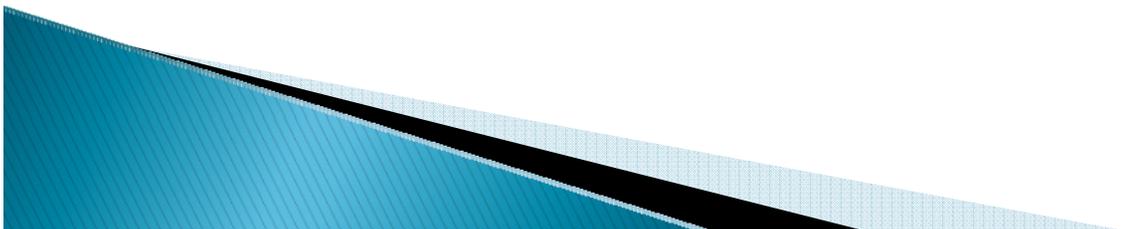
537 F.3d 1357 (Fed. Cir. 2008)

- After disclosing in a letter to patent counsel prosecuting the application that the invention was already known in China, the applicant switched law firms.
- Asserting the inequitable conduct defense, defendant argued that the applicant switched firms to avoid disclosing the letter.
- Defendant must prove intent to deceive and materiality by clear & convincing evidence.
- Only after both elements are proven will the court balance the equities to determine whether the evidence warrants a finding of inequitable conduct.
 - Defendant failed to prove that the applicant switched firms due the existence of the material information.



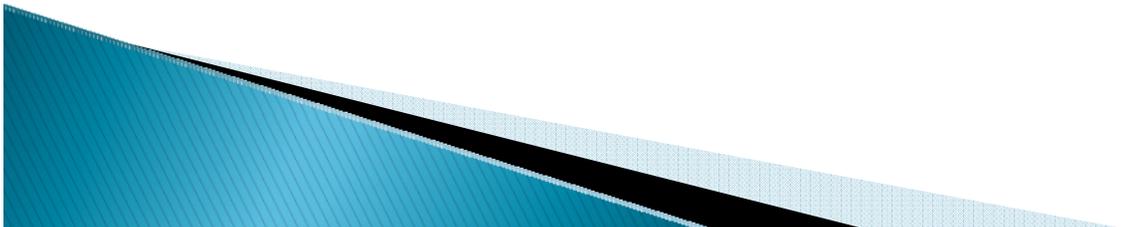
Consequences of Inequitable Conduct Doctrine

- Increasing litigation cost
- Discouraged settlements
- Expanded discovery
- Cluttering up PTO
 - Applicants disclose too much prior art
 - Applicants do not explain its significance
- Plague – overused as a defense
- Atomic Bomb – rendering entire patent unenforceable



Inequitable Conduct Doctrine Problems

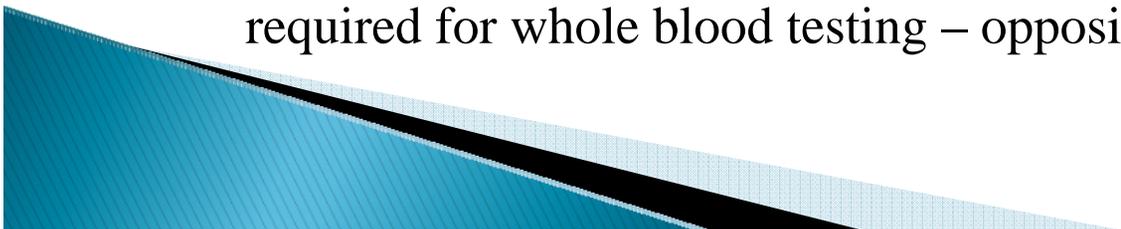
- What is the standard for materiality?
 - But-for (objective or subjective)
 - But it may have
 - Reasonable examiner
 - Rule 56
- Under what circumstances should intent be inferred from materiality?
- Sliding scale? – permitting a finding of inequitable conduct based on a reduced showing of intent if the record contained a strong showing of materiality or vice versa
- Shown have known



Therasense v. Becton, Dickinson

649 F.3d 1276 (Fed. Cir. 2011)

- Technology involved disposable blood glucose test strips for measuring the amount of glucose in whole blood using a *membraneless* electrode.
- A prior art reference to the patentee's patent contained a protective membranes covering the electrode. The specification stated a membrane was "optionally, but preferably" included in the test strip.
- Distinguishing the prior art, the patentee's expert argued that one of ordinary skill in the art would understand that "optionally, but preferably" meant the invention required a membrane.
- During prosecution of its European companion application, the patentee previously argued that the membrane was *not* absolutely required for whole blood testing – opposite argument.

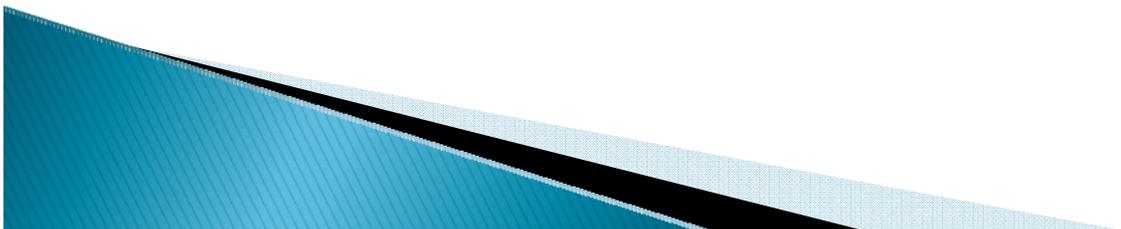


Inequitable Conduct Doctrine Revamped

Therasense v. Becton, Dickinson

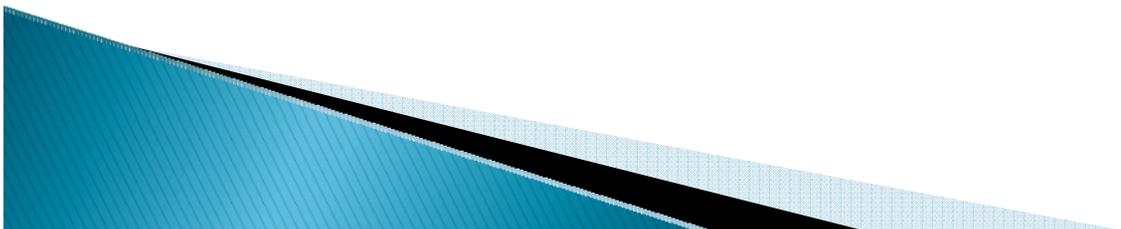
649 F.3d 1276 (Fed. Cir. 2011)

- *Therasense* was the first inequitable conduct case heard by the Federal Circuit *en banc* since *Kingdown* (1988).
- The *Therasense* court tightened the standards for finding both intent and materiality in order to redirect a doctrine that has been overused to the detriment of the public:
 - But-for Materiality
 - Intent
 - Exception – Affirmative egregious misconduct



“But-for” Materiality Defined

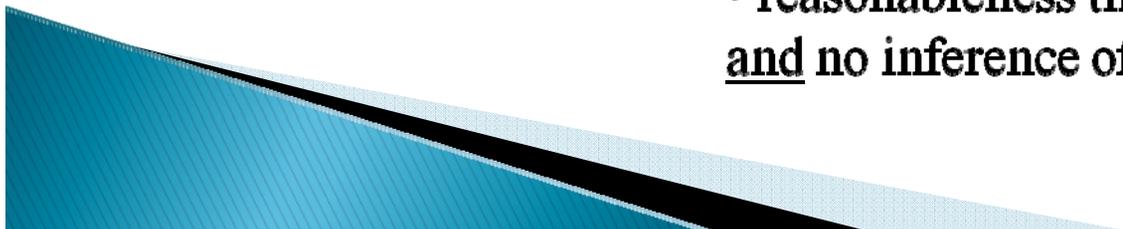
- “[w]hen an applicant fails to disclose prior art to the PTO, that prior art is but-for material if the PTO would not have allowed a claim had it been aware of the undisclosed prior art.”
- Court required to be proved by clear and convincing evidence.
- PTO will:
 - Apply the preponderance of the evidence standard
 - Afford claims the broadest reasonable interpretation



But-For Materiality Analysis

Material Information Analysis

- Can the reference invalidate the claims?
 - Yes = Material information
 - Submit information (IDS)
 - No
 - Apply the PTO “But-for” analysis for unpatentability
 - Yes = Material Information
 - Submit information (IDS)
 - No
 - Apply egregious misconduct analysis
 - Yes = Material Information
 - reasonableness that information is not material and no inference of intent to deceive



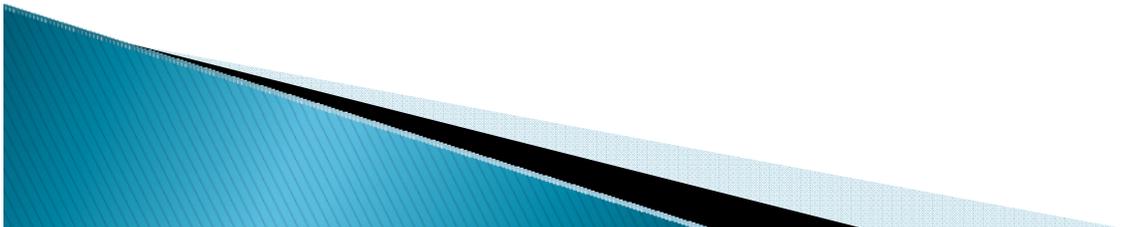
Affirmative Egregious Misconduct Exception

- Exception to materiality prong
- Unclean Hands
 - Deliberately planned and carefully executed scheme to defraud the PTO and courts.
 - Filing an unmistakably false affidavit. *Rohm & Haas Co. v. Crystal Chem. Co.*, 722 F.2d 1556 (Fed. Cir. 1983).
 - Applicant described examples in specification as though they were actually conducted. *Hoffman La Roche v. Promega* , 323 F.3d 1354 (Fed. Cir. 2003).
- Contrast – Not affirmative egregious misconduct:
 - Nondisclosure of prior art references to the PTO
 - Failure to mention prior art references in an affidavit



Specific Intent to Deceive

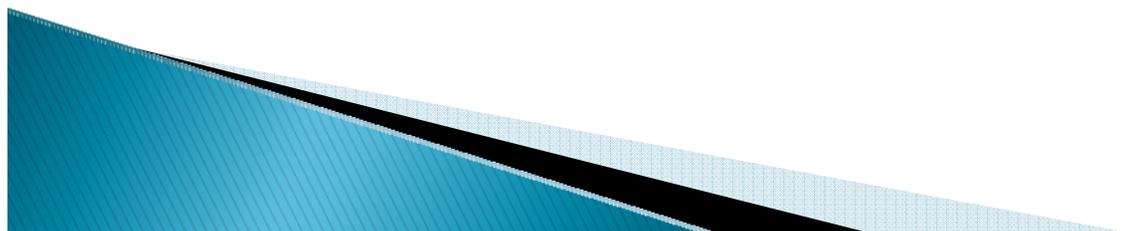
- Must be proved by **clear and convincing** standard
 - Applicant knew of the reference;
 - Applicant knew of the materiality of the reference AND
 - Applicant made *deliberate decision* to withhold a *known* material reference.
- Negligence is **NOT** enough
 - Applicant knew of the reference
 - Applicant should have known of its materiality and
 - Decided not to disclose to the PTO
- **Inference** of intent
 - Direct evidence – yes
 - Circumstantial evidence - depends



Proposed Amended 37 CFR § 1.56

On July 21, 2011, the PTO issued proposed rules that would amend Rules 56(b) and 555(b) in light of *Therasense*.

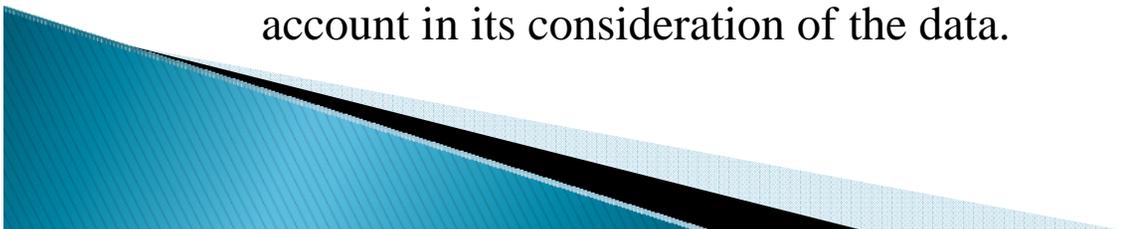
- Section 1.56(b) as proposed to be amended would provide that information is material to patentability if it is material under the standard set forth in *Therasense*, and that information is material to patentability under *Therasense* if:
 - The PTO would not allow a claim if it were aware of the information, applying the preponderance of the evidence standard and giving the claim its broadest reasonable construction; or
 - The applicant engages in affirmative egregious misconduct before the PTO as to the information.



Post *Therasense* Specific Intent

Ethypharm v. Abbott, 2011 U.S. District Lexis 93879 (D. Del., August 23, 2011).

- Ethypharm counterclaimed “sham litigation” based on inequitable conduct defense alleging Abbott’s chief scientist failed to inform the PTO that data relied on during prosecution was inherently unreliable.
 - Ethypharm argued defense withheld results from 16 other data sets
- Court only addressed “specific intent”
 - Ethypharm must show by clear & convincing evidence that defendant knew of the unreliability of the data, knew that it was material and made a deliberate decision to withhold this information from the PTO.
 - Ethypharm only suggested that defendant’s omission was grossly negligent or negligent – “should have known” standard.
- Although the court considered testimony that one data set can never provide a complete picture, the court concluded that the PTO would have taken this into account in its consideration of the data.



Post *Therasense* Knowledge & Intent

Abaxis, Inc. v. Cepheid, 2011 U.S. District Lexis 95589 (N.D. Calif., August 25, 2011).

- Court dismissed inequitable conduct claim for failure to sufficiently plead facts to support a reasonable inference of knowledge and intent.
- Cepheid asserted Abaxis' patent counsel knowingly and intentionally failed to disclose prior art reference that would have rendered 4 patents unpatentable due to anticipation and/or obviousness.
 - PCT search report for a different application cited the prior art reference.
 - Counsel filed supplemental disclosure statement for U.S. counterpart attached with the prior art reference.
- Applying *Exergen* and *Therasense*:
 - Did the individual with "specific intent" make an affirmative misrepresentation of a material fact, fail to disclose material information or submit false material information?
 - Court may not infer intent solely from materiality.
 - Proving that the applicant knew of reference, should have known of its materiality, and decided not to submit it to the PTO, does not prove specific intent to deceive.



Post *Therasense* Cases Attorney Fees

Pfizer v. Teva, 2011 U.S. District Lexis 111961 (E.D. Va., Oct. 17, 2011).

- Pfizer filed infringement suit against Teva regarding Viagra patent.
- Teva asserted inequitable conduct defense.
 - June 17, 2011, Teva motioned to amend its answer & counterclaim to change allegations regarding the inequitable conduct claim.
- Court found no “but-for” materiality inequitable conduct.
 - Pfizer filed motion for attorney fees asserting Teva’s inequitable conduct claim was baseless under *Therasense*
 - Teva counterclaimed that Pfizer’s misconduct was “egregious” under *Therasense*.
- Court awarded Pfizer \$372 million for attorney fees incurred after *Therasense*.



Post *Therasense* Cases Intent to Deceive

Apotex v. Cephalon, 2011 U.S. District Lexis 12589 (E.D. Pa, Oct. 31, 2011).

- After filing ANDA for the generic version of Provigil used for sleep disorders, Apotex sought declaratory action against Cephalon.
- Material Information
 - In 1986, Lafon, a French company began testing and manufacturing small particle modafinil, the primary chemical compound of Provigil.
 - In 1992, Cephalon entered into supply & license agreement with Lafon.
 - In 2001, Cephalon purchased Lafon.
 - Cephalon failed to disclose its relationship with Lafon.
- Intent to Deceive
 - Cephalon told PTO that it had modified the particle size of the claimed product beyond the prior art
 - Cephalon had not changed, modified or improved the product after it received it from Lafon.



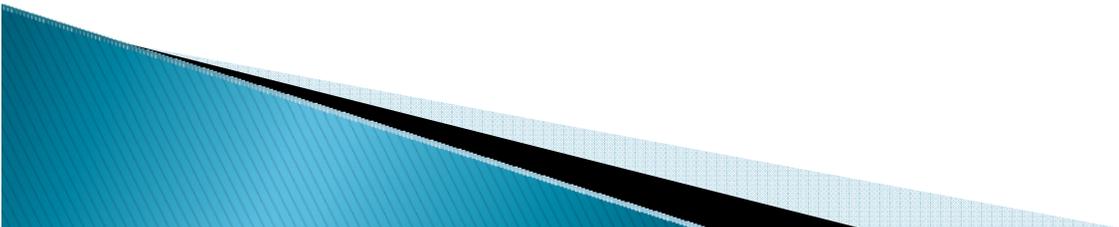
Impact of *Therasense* on Litigation

- Decrease inequitable conduct allegations?
 - *Exergen* – heighten pleadings requirement
- Increase in grant summary judgment no inequitable conduct?
 - *Therasense* – heightened “intent to deceive”
- **Circumstantial Evidence** – more difficult to prove intent
 - Any inference of intent to deceive must be the single most reasonable inference drawn from the evidence.
 - When there are multiple reasonable inferences that may be drawn, intent to deceive cannot be found.
 - Lack of good faith explanation for withholding reference is insufficient.



***Post Therasense* Issues in Prosecution**

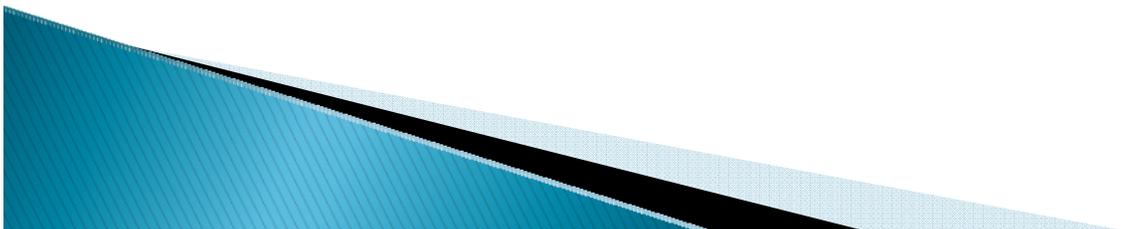
- Information Disclosure Statements
 - What is included information should be disclosed?
 - How should it be disclosed?
 - Who decides what is disclosed?
- Inventorship
- Declarations



Patent Reform Impact on Inequitable Conduct

Supplemental Examination:

- Patent owner can request PTO to consider, reconsider or correct any information believed to be relevant.
- PTO will reexamine the patent if it finds a substantially new question of patentability.
- Patent cannot later be held unenforceable based on information that was considered during supplemental examination.
- May allow patent owner to strengthen patent before litigation by preventing potential charges of inequitable conduct.

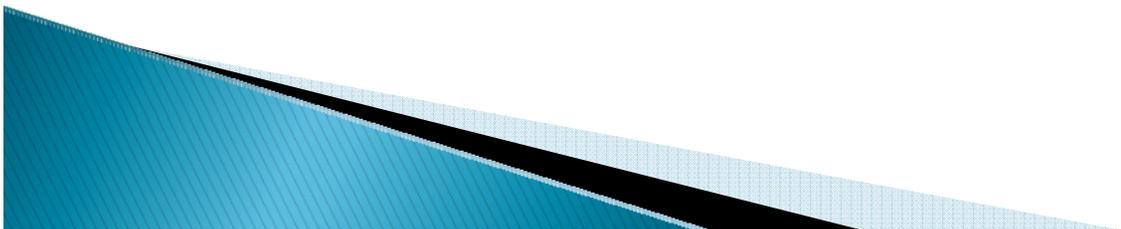


Patent Reform Impact on Inequitable Conduct

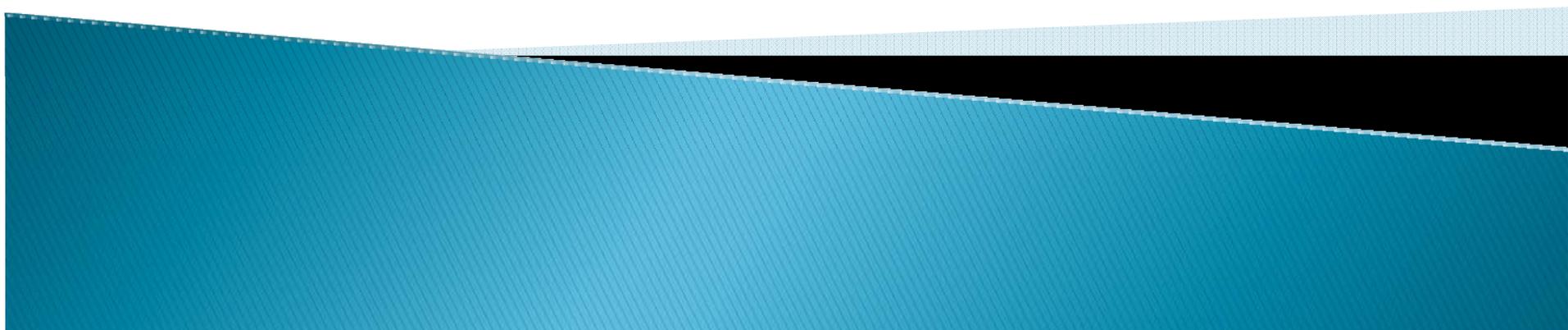
Effective September 16, 2012 – applies to all patents retroactively issued before, on or after the effective date.

- **Limitation:**

- Not effective if inequitable conduct previously alleged with particularity in a pending litigation or ANDA Paragraph IV certification.
- Not effective in International Trade Commission (ITC) unless supplemental examination and reexamination concluded before ITC action was filed.

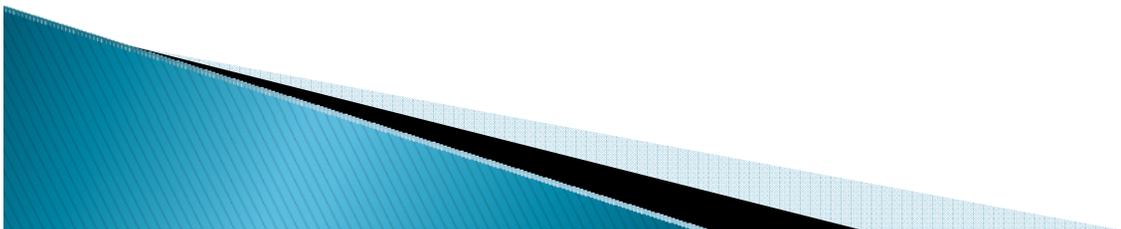


Best Mode



35 U.S.C. § 112

- ▶ The specification shall contain:
 - a written description of the invention of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and
 - shall set forth the *best mode* contemplated by the inventor of carrying out his invention.

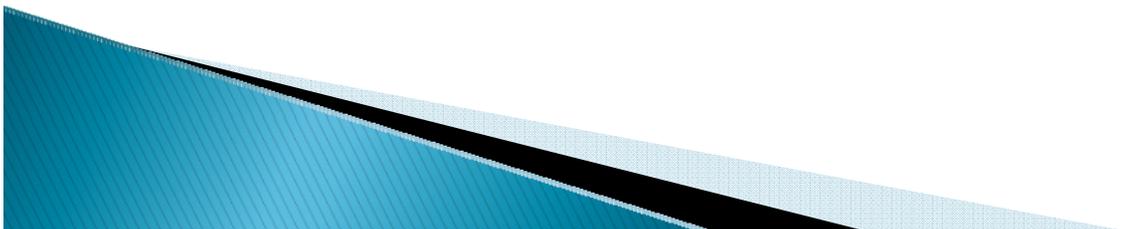


Best Mode Requirement - 35 U.S.C. § 112

- ▶ Subjective test:
 - At the time the application was filed, did the inventor possess a best mode for practicing the invention? This inquiry focuses on the inventor's state of mind at the time of filing.

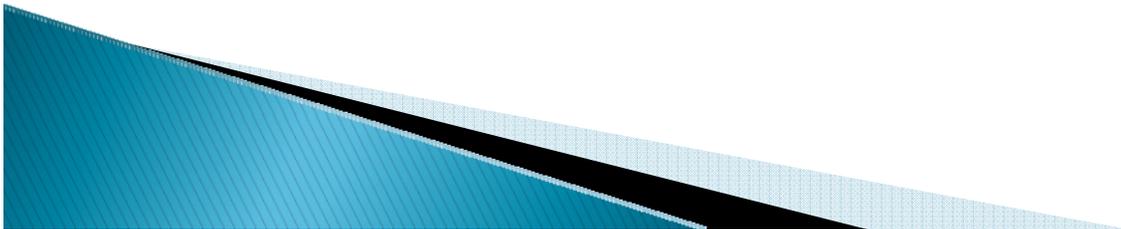
- ▶ Objective test:
 - Does the written description disclose the best mode such that a person skilled in the art could practice it? This inquiry, focusing on the scope of the claimed invention and the level of skill in the art.

 - *Eli Lilly & Co. v. Barr Laboratories Inc.*, 251 F.3d 955 (Fed. Cir. 2001).



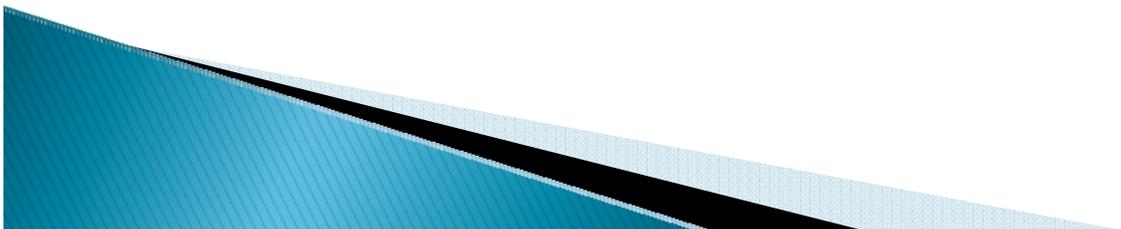
Best Mode – Inventor's Mind

- ▶ Where an inventor knows of a specific material that will make possible the successful reproduction of the effects claimed by the patent, but does not disclose it, speaking instead in terms of broad categories, the best mode requirement has not been satisfied.



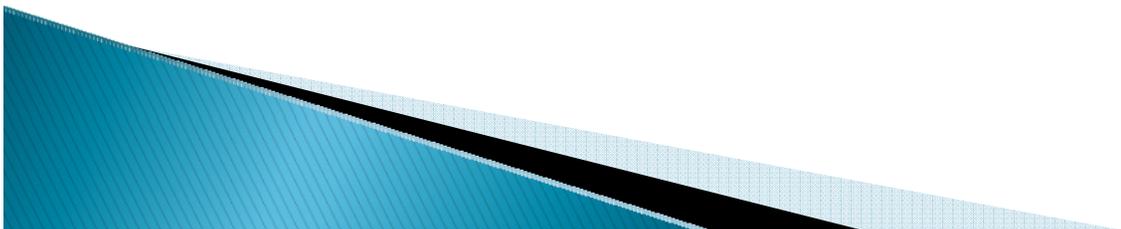
Best Mode – Timing

- ▶ The failure to disclose a better method will not invalidate a patent if the inventor, at the time of filing the application, did not know of the better method OR did not appreciate that it was the best method.



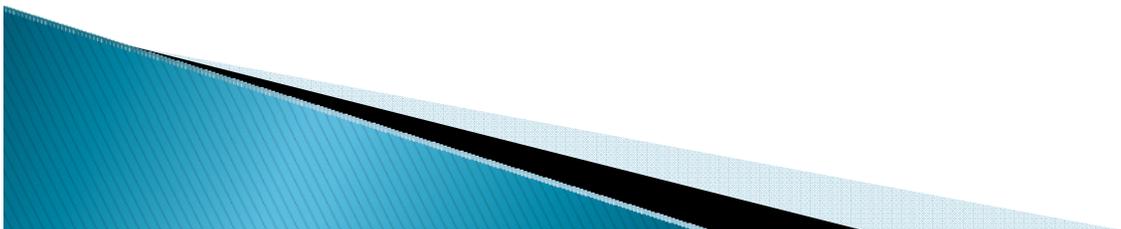
Best Mode – Prior to AIA

- ▶ Failure to disclose the best mode was a basis for rendering a patent invalid.
- ▶ If the failure to set forth the best mode in a patent disclosure is the result of inequitable conduct (e.g., where the patent specification omitted crucial ingredients and disclosed a fictitious and inoperable slurry as Example 1), not only is that patent in danger of being held unenforceable, but other patents dealing with the same technology that are sought to be enforced in the same cause of action are subject to being held unenforceable.



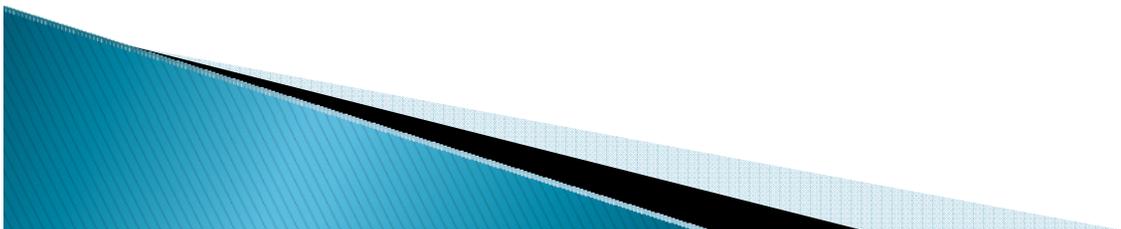
Elimination of the Best Mode Defense

- ▶ Effective September 16, 2011:
- ▶ Section 15 of the AIA eliminates the failure to comply with the best mode requirements of 35 U.S.C. § 112 as a basis for invalidating a patent or rendering it unenforceable.
- ▶ **HOWEVER**, this **does not** change the requirement of 35 U.S.C. § 112 to disclose the best mode.



Significance of Best Mode

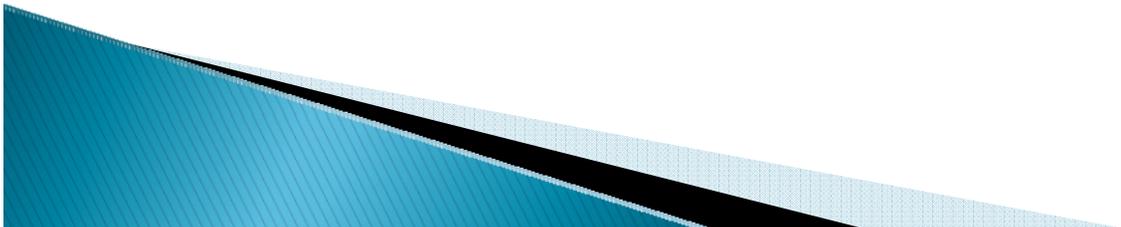
- ▶ Other provisions require full disclosure
- ▶ Was the standard too subjective?
- ▶ What information did the inventor know and initially withheld?



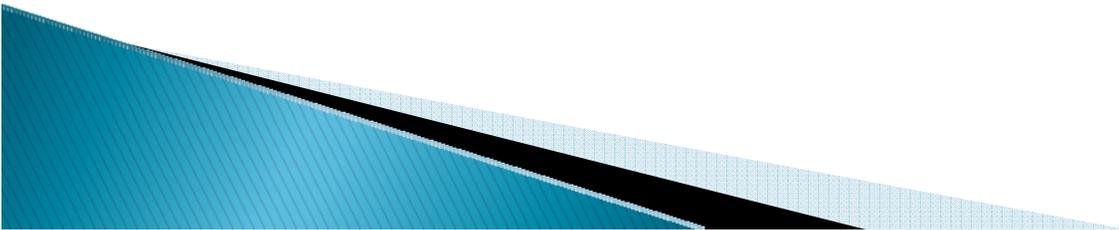
Ethical Considerations

- ▶ 35 U.S.C. § 32 – *intent to defraud the PTO*
 - Suspension or exclusion from practice before the PTO.

- ▶ 35 U.S.C. § 252(e) – *if material fraud is found:*
 - Director is empowered to take any action otherwise authorized (including cancelling a claim or claims under 35 U.S.C. § 307)
 - and
 - Shall refer the matter to the Attorney General.



QUESTIONS



THANK YOU!

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