

For:



Update on Patents:  
Inequitable Conduct and  
Claim Construction  
May 8, 2006



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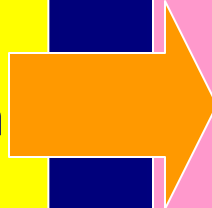
# OUTLINE

- I. Update on Claim Construction in the CAFC
  - A. CAFC Phillips decision and “framework” cases therein
  - B. Look to specification (*Chimie, Aquatex*)
  - C. Pros. history (*Salazar*)
  - D. Try to draft claim with an objective anchor (*Datamize*)
  - E. “Appropriate weight” of dictionaries (*Terlep*)
  - F. “Context” over ordinary meaning (*Nystrom*)
  - G. Strange Message (*Wilson Sporting Goods, Lava Trading*)
  
- II. Inequitable Conduct Update
  - A. Assertions (*Purdue v. Endo, Atofina*)
  - B. Test Results (*Novo Nordisk, Kao*)
  - C. Connections (*Ferring*)

# CLAIM CONSTRUCTION

# Claim Construction

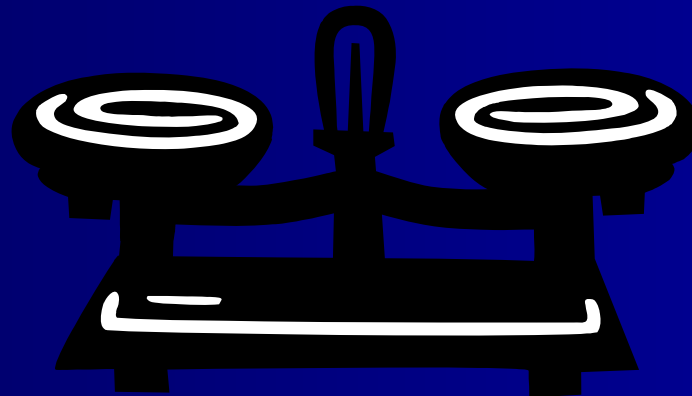
- **First, construe claims**
  - **Intrinsic evidence**
    - **Claims**
    - **Specification**
    - **Prosecution history, if in evidence**
  - **Extrinsic evidence, only if necessary**



- **Then, compare claims as construed to accused product (infringement analysis) or prior art (invalidity analysis) or written description (§ 112 support analysis)**
  - **Literal infringement**
  - **DOE/PHE**

# Principles In Tension

- **may not read into a claim a limitation from a preferred embodiment**
  
- **But if the preferred embodiment is described in the specification as the invention itself, the claims are not necessarily entitled to a scope broader than that embodiment**



# Phillips v. AWH Corp., 415 F.3d 1303 (Fed. Cir. 2005)(en banc)

- Issue = extent to which it is proper to resort to and rely on a patent's specification in seeking to ascertain the proper scope of its claims?



## Phillips v. AWH Corp. (con't)

- The ordinary and customary meaning of a claim term is the meaning the term would have to a person of ordinary skill in the art (“POSA”) [who!] in question at the time of the invention, i.e., as of the effective filing date of the patent application [when!].
- The inquiry into how a POSA understands a claim term: a beginning objective baseline.

## Phillips v. AWH Corp. (con't)

- Importantly, POSA is deemed to have read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification.
- Court then looks to sources available to the public that show what POSA would have understood
- Those sources include the words of the claims, the specification, the prosecution history, and extrinsic evidence.

## Phillips v. AWH Corp. (con't)

- The specification is always highly relevant to claim construction and is the **single best guide** to the meaning of a claim term in dispute.

## Phillips v. AWH Corp. (con't)

- The prosecution history, if in evidence, can indicate how the PTO and the inventor understood the patent, but it is not a tool for expanding the specification



## Phillips v. AWH Corp. (con't)

- Courts are authorized to rely on extrinsic evidence
- But it is **less** significant than the intrinsic record in determining the meaning of claim language.
- Examples of extrinsic evidence: dictionaries and treatises, expert testimony
- Expert testimony can be useful, such as to ensure that the court's understanding is consistent with that of POSA or to establish a particular meaning of a term.

## Phillips v. AWH Corp. (con't)

- Discussion of Texas Digital Systems, Inc. v. Telegenix, Inc., 308 F.3d 1193 (Fed. Cir. 2002)
  - “Although the concern expressed by the court in Texas Digital (about importing limitations from the specification) was valid, the methodology it adopted placed too much reliance on extrinsic sources such as dictionaries, treatises, and encyclopedias and too little on intrinsic sources, in particular the specification and prosecution history”



## Phillips v. AWH Corp. (con't)

- Discussion of Texas Digital (con't)
  - “Texas Digital approach limits the role of the specification in claim construction to serving as a check on the dictionary meaning of a claim term if the specification requires the court to conclude that fewer than all the dictionary definitions apply, or if the specification contains a sufficiently specific alternative definition or disavowal.”
  - Such an approach “improperly restricts the role of the specification in claim construction” because the spec is the single best guide and acts as a dictionary when it expressly or implicitly defines terms.

## Phillips v. AWH Corp. (con't)

- “The risk of systematic overbreadth is greatly reduced if the court instead focuses at the outset on how the patentee used the claim term in the claims, specification, and prosecution history, rather than starting with a broad definition and whittling it down.”

## THE CASES BLESSED BY THE EN BANC PHILLIPS COURT

- Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 39 U.S.P.Q.2d 1573 (Fed. Cir. 1996): all about implicit meaning
  - Claims limitation at issue: “solder reflow temperature”
  - specification showed three types of solder and the claims were not limited to any particular solder and thus not to any particular solder with any particular liquidus temperature
  - DC: JMOL of no infringement
    - construed “solder reflow temperature” as 183°C
    - **Did not indicate which evidence it relied upon but wait until you hear what that evidence was!**

# THE CASES BLESSED BY THE EN BANC PHILLIPS COURT

- Vitronics (con't)
  - The specification discloses a method for the reflow soldering of surface mounted devices to a printed circuit board. After various steps, there is a last heating zone, where the solder reaches a temperature high enough to cause the solder to melt and reflow, but the devices themselves are maintained below the solder reflow temperature.
  - Claim 1: “heating said board and said solder to a solder reflow temperature ...to cause said solder to reflow and solder said devices to said board while maintaining the temperature of said devices below said solder reflow temperature.

# THE CASES BLESSED BY THE EN BANC PHILLIPS COURT

- Vitronics (con't)
  - Vitronics: “solder reflow temperature” means “peak reflow” temperature, i.e., temperature during the period it is reflowing not the “liquidus” temperature at which the solder begins to melt. That is a temperature approximately 20°C above the liquidus temperature, at which the solder is completely melted and moves freely
  - Conceptronic: “solder reflow temperature” means 183°C, i.e., the liquidus temperature of a particular type of solder known as 63/37 (Sn/Pb) solder

# THE CASES BLESSED BY THE EN BANC PHILLIPS COURT

- Vitronics (con't)

- Vitronics urged that although in isolation the term “solder reflow temperature” might be ambiguous, the specification showed that, as used in the claim, solder reflow temperature means peak reflow temperature rather than the liquidus temperature
  - Pointed to a preferred embodiment, where it was stated that liquidus temp was about 190° C and a peak reflow temp of about 210° - 218° C. The Example stated that the temperature of the solder was raised to 210° C, and the device was raised to 195°C, above the liquidus temperature.
  - If “solder reflow temperature” meant liquidus temperature (190°C) , the example would not be covered by the claims because the temperature of the device (195°C) would not be below the liquidus temperature

# FRAMEWORK FOR CLAIM CONSTRUCTION

- Vitronics (con't)
  - FC: Reversed and remanded
    - focused on the specification to come up with a claim construction -> "***Usually, it is dispositive; it is the single best guide to the meaning of a disputed term.***" (emphasis added)
    - Seems to presume that the spec will be dispositive as to the meaning of a claim term

# FRAMEWORK FOR CLAIM CONSTRUCTION

- Vitronics (con't)
  - **FC: Intrinsic over extrinsic**
    - In most situations, an analysis of the intrinsic evidence alone will resolve any ambiguity in a disputed claim term. In such circumstances, it is improper to rely on extrinsic evidence. **[note the proscription!!]**
    - The claims, specification, and file history, rather than extrinsic evidence, constitute the public record of the patentee's claim, a record on which the public is entitled to rely and a guide that entitles competitors to apply the established rules and design around the claimed invention. **[notice to the public: important theme]**

# FRAMEWORK FOR CLAIM CONSTRUCTION

- Vitronics (con't)
  - FC: Intrinsic over extrinsic
    - Allowing the public record to be altered or changed by extrinsic evidence introduced at trial, such as expert testimony, would make this right meaningless.
    - Notice, notice, notice: extrinsic undermines notice

# FRAMEWORK FOR CLAIM CONSTRUCTION

- Vitronics (con't)
  - FC: Instructive intrinsic claim construction
    - to be consistent with the specification and preferred embodiment, claim 1 must be construed such that the term "solder reflow temperature" means the peak reflow temperature
    - "if 'solder reflow temperature' were defined to mean liquidus temperature, a preferred (and indeed only) embodiment in the specification would not fall within the scope of the patent claim. Such an interpretation is rarely, if ever, correct and would require highly persuasive evidentiary support, which is wholly absent in this case."
    - **That should have ended the district court's analysis!**

# FRAMEWORK FOR CLAIM CONSTRUCTION

- Vitronics (con't)
  - FC: Claim construction
    - DC erred in relying on extrinsic evidence when intrinsic evidence provided the meaning of the claim term”
      - **“where the patent documents are unambiguous, expert testimony regarding the meaning of a claim is entitled to no weight.”**
      - “Because the specification clearly and unambiguously defined the disputed term in the claim, reliance on this extrinsic evidence was unnecessary and, hence, legally incorrect.”

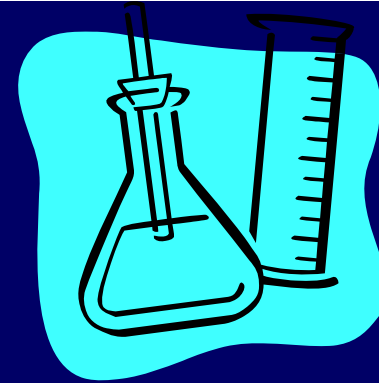
# FRAMEWORK FOR CLAIM CONSTRUCTION

- Vitronics (con't)
  - FC: Claim construction
    - Nor may the inventor's subjective intent as to claim scope, when unexpressed in patent documents, have any effect.
    - Note fn. 6: dictionaries are extrinsic evidence but may be consulted by judges and relied so long as the dictionary definition does not contradict any definition found in or ascertained by a reading of the patent documents.

# FRAMEWORK FOR CLAIM CONSTRUCTION

- Vitronics (con't)
  - FC: Claim construction
    - A court in its discretion can admit and rely on prior art, whether or not in the specification or file history.
    - The prior art can help to demonstrate how a disputed term is used by those skilled in the art.
    - As compared to expert testimony, prior art may be more indicative of what those skilled in the art believe a term means.
    - But that evidence is improper if one can understand from a careful reading of the public record.
    - The prior art cannot be used to vary claim terms from how they are defined, even implicitly, in the spec or file history.

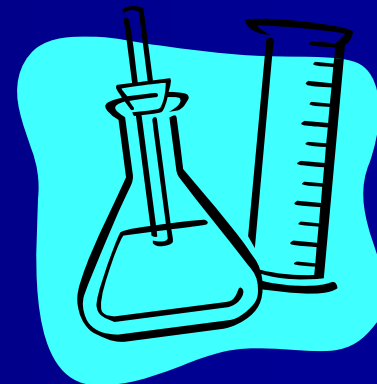
## Post-Phillips



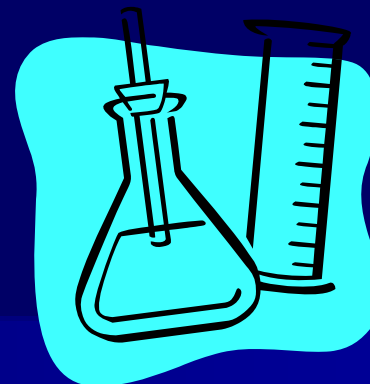
- Chimie v. PPG Industries, 402 F.3d 1371 (Fed. Cir.), reh'g denied (May 24, 2005)
  - Limitation at issue: “dust-free and non-dusting”
  - DC: granted SJ of noninfringement
    - Construed “dust-free and non-dusting” according to standard measure set forth in specification (“DIN 53 583”)

# Post-Phillips

- Chimie (con't)
  - specification contains ten examples of silica products and the results of several tests making comparisons among those products
  - tests conducted included a test using the DIN 53 583 standard



# Post-Phillips



## ■ Chimie (con't)

### – FC: Affirmed

- DC properly construed the disputed claim terms
- relative phrase which can only be understood in comparison to the prior art -> written description to determine the scope
- reference to the DIN test results reconciled the ambiguous claim language with the inventor's disclosure
- "the only articulation of the dustiness of the claimed invention is made with reference to the DIN 53 583 standard"

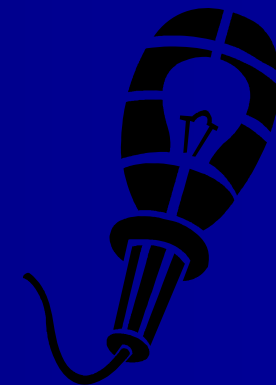
# Prosecution History: Does Silence = "Notice" To Public?

- Salazar v. Procter & Gamble Co., 414 F.3d 1342 (Fed. Cir. 2005)
  - Invention: toothbrush
  - DC: granted SJ of noninfringement
  - FC: Vacate and remand
    - DC erred in using patent examiner's Reasons of Allowance to exclude nylon from the scope of the claim term "elastic"
    - FC: "This court refuses to create a rule or presumption that the applicant in this case disavowed claim scope by silence."
      - "Examiner's unilateral remarks alone do not affect the scope of the claim, let alone show a surrender of claimed subject matter that cannot be recaptured under the doctrine of equivalents"



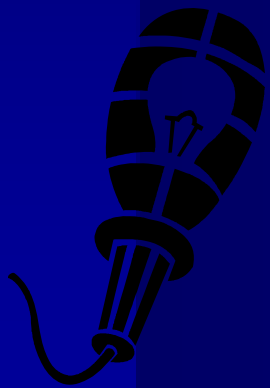
## "Appropriate Weight" Of Dictionaries

- Terlep v. The Brinkman Corp., 418 F.3d 1379 (Fed. Cir. 2005)
  - claim term at issue: "a first *clear* plastic tubular holder"
  - DC construed "clear" to mean "transparent"
  - no accused products had transparent holder
  - Terlep argued should be construed as "permitting passage of light"
    - cover translucent too



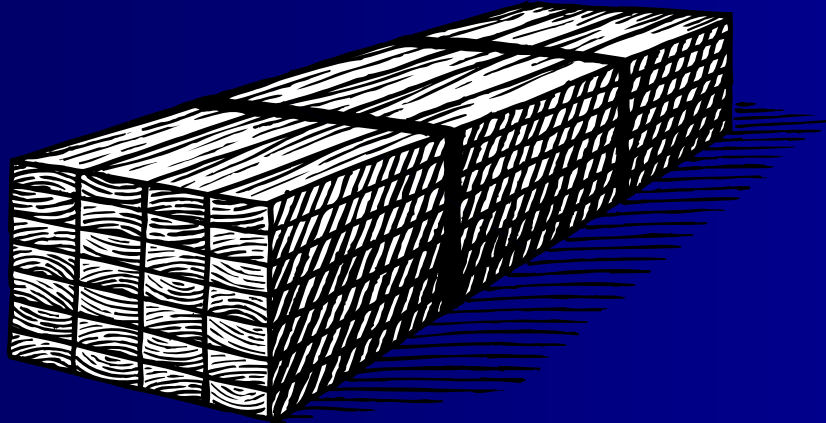
## "Appropriate Weight" Of Dictionaries

- Terlep (con't)
  - DC: granted SJ of non-infringement
  - FC: Affirmed
    - DC properly construed "clear"
    - "Interpreting the asserted claims entails a review of the intrinsic evidence, which consists of the claim language, the written description, and the prosecution history. [citing Vitronics]. ...Extrinsic evidence such as dictionaries also 'may be considered if the court deems it helpful in determining the true meaning of the language used in the patent claims,' ... provided the court 'attach[es] the appropriate weight . . . to those sources in light of the statutes and policies that inform patent law,' [quoting Phillips]."



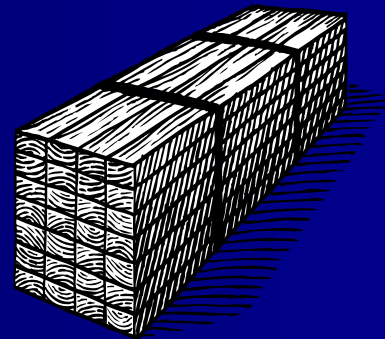
# “Context” Of Patent Overrides Ordinary Meaning

- Nystrom v. Trex Co., 424 F.3d 1136 (Fed. Cir. 2005)
  - Claim 1: A **board** for use in constructing a flooring surface for exterior use...



# “Context” Of Patent Overrides Ordinary Meaning

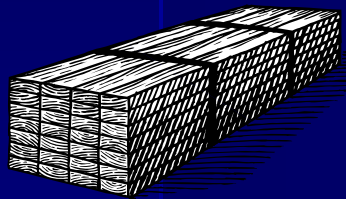
- Nystrom (con’t)
  - DC: “board” = “made from wood cut from a log.”
    - Nystrom limited the scope of the claim term by statements in the written description that a board is cut or obtained from a log
    - Granted SJ of noninfringement and invalidity



# “Context” Of Patent Overrides Ordinary Meaning

- **Nystrom** (con’t)

- FC: Affirmed SJ non-infringement; reversed grant of SJ invalidity

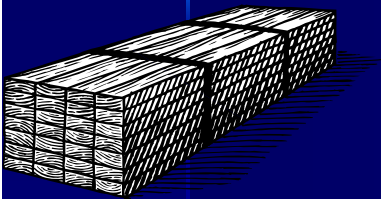


- Although no language in claim 1 describing “board” as only wood, context of the written description and prosecution history **“reflects Nystrom’s consistent use of the term board to refer to wood decking materials cut from a log.”**

- Background of the Invention -> wood decking materials cut from logs, even though it acknowledges that other materials exist.
- Throughout the written description, Nystrom consistently used the term “board” to describe wood decking material cut from a log

## "Context" Of Patent Overrides Ordinary Meaning

- Nystrom (con't)

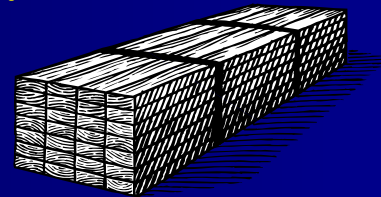


- FC: although ordinary meaning of "board" encompasses both a piece of cut wood or sawn timber and a similarly-shaped item made of a rigid material, **"as explained in Phillips, Nystrom is not entitled to a claim construction divorced from the context of the written description and prosecution history."**

- "Nystrom consistently used the term 'board' to refer to wood cut from a log. Although there was no clear disavowal of claim scope, there was nothing in the intrinsic record to support the conclusion that a skilled artisan would have construed the term 'board' more broadly than a piece of construction material made from wood cut from a log."

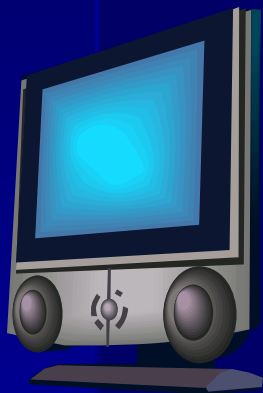
# "Context" Of Patent Overrides Ordinary Meaning

- Nystrom (con't)
  - "The written description and prosecution history consistently use the term "board" to refer to wood decking materials cut from a log. ... **it is improper to read the term to encompass a broader definition simply because it may be found in a dictionary, treatise, or other extrinsic source.**



# Need An Objective Standard

- Datamize, LLC v. Plumtree Software, Inc., 417 F.3d 1342 (Fed. Cir. 2005)
  - limitation at issue: “aesthetically pleasing”
  - DC: granted SJ of invalidity
  - FC: Affirmed
    - Patentee failed to provide one of ordinary skill in the art with any objective way to determine whether an interface screen is “aesthetically pleasing.”
    - “The scope of claim language cannot depend solely on the unrestrained, subjective opinion of a particular individual purportedly practicing the invention.”
    - **Some objective standard must be provided in order to allow the public to determine the scope of the claimed invention.**



# Patent Profanity Cost The Patentee

- Atofina v. Great Lakes Chemical Corp., 441 F.3d 991 (Fed. Cir. 2006)



- limitation at issue: “chromium catalyst”
- DC granted judgment of no infringement
  - construed claim based on specification, prosecution history, and dictionaries
  - Great Lakes’ catalyst contained a non-chromium substance
- FC: Affirmed
  - Statements in specification: “it is **necessary** to have a catalyst containing solely chromium.”

## STRANGE MESSAGES

- Wilson Sporting Goods Co. v. Hillerich & Bradsby Co., 442 F.3d 1322 (Fed. Cir. 2006)
  - Claim: 1. A bat, comprising: ...an insert ... separated from the tubular frame by a gap[.]
  - DC granted H & B's DJ that its bats did not infringe Wilson's patent
  - FC: vacate and remand because of erroneous claim construction

## HERE'S WHERE IT GETS STRANGE

- Wilson Sporting Goods (con't)
  - “Therefore, in reviewing claim construction in the context of infringement, the legal function of giving meaning to claim terms always takes place in the ***context of a specific accused infringing device or process***. While a trial court should certainly not prejudge the ultimate infringement analysis by construing claims with an aim to include or exclude an accused product or process, knowledge of that product or process provides meaningful context for the first step of the infringement analysis, claim construction.”

## HERE'S WHERE IT GETS STRANGE

- Wilson Sporting Goods (con't)
  - “In this case, despite entry of a final judgment, neither the trial court nor the parties supplied this court with any information about the accused products. Thus, this record affords this court no opportunity to compare the accused products to the asserted claims. Accordingly, this court cannot assess the accuracy of any infringement or validity determination. Furthermore, this sparse record lacks the complete context for accurate claim construction. Thus, without a record of the accused products, this appeal assumes many attributes of a proceeding seeking an advisory opinion on the scope of the '398 patent.”

# SUGGESTIONS FOR REMAND

- Wilson Sporting Goods (con't)
  - ordinary and customary meaning of “annular”
  - defines “gap” as “a separation”
  - “insert” can be defined broadly enough to encompass both a hollow and a solid insert, and yet have the same meaning in all claims
    - ordinary and customary meaning

## NO "CONTEXT"

- Wilson Sporting Goods (con't)
  - "Unfortunately this court lacked the full context of this infringement action and the claim construction component of infringement because the record on appeal contains no description of the accused infringing devices. Without that additional context, this court cannot fully and confidently review the infringement judgment, including its claim construction component."

# “AWARENESS”

- Wilson Sporting Goods (con’t)
  - **“This court, of course, repeats its rule that “claims may not be construed with reference to the accused device.”**  
... The rule, however, does not forbid awareness of the accused product or process to supply the parameters and scope of the infringement analysis, including its claim construction component. ... In light of these principles, if the litigants cannot themselves inform a trial court of the specific issues presented by the infringement inquiry—that is, issues of the breadth of the claim construction analysis and the most useful terms to facilitate that defining process—then a trial court may refer to the accused product or process for that context during the process.”

# "CONTEXT" OF ACCUSED PRODUCT

- Lava Trading, Inc. v. Sonic Trading Management, LLC, --F.3d--, Nos. 05-1177, -1192 (Fed. Cir. April 19, 2006)
  - FC: Vacated district court's claim construction and remanded
  - "this record on appeal does not supply any meaningful comparison of the accused products to the asserted claims. Without knowledge of the accused products, this court cannot assess the accuracy of the infringement judgment under review and lacks a proper context for an accurate claim construction. **'While a trial court should certainly not prejudge the ultimate infringement analysis by construing claims with an aim to include or exclude an accused product or process, knowledge of that product or process provides meaningful context for the first step of the infringement analysis, claim construction.'** [citations omitted] **Without the vital contextual knowledge of the accused products or processes, this appeal takes on the attributes of something akin to an advisory opinion on the scope of the '982 patent."**

# Post-Phillips Claim Construction

- On Demand Machine Corp. v. Ingram Industries, Inc., --F.3d--, Nos. 05-1074, -1075, -1100 (Fed. Cir. Mar. 31, 2006)
  - Patent for "System and Method of Manufacturing a Single Book Copy"
  - Claim 8. A method of **high speed manufacture of a single copy of a book** comprising the steps of:
    - [2] storing the text of a plurality of books in a computer,
    - [3] storing **sales information** relating to said plurality of books in a computer, [
    - [4] providing means for **a customer** to visually review said sales information, ...,
    - [7] **printing the text of said selected one of said books on paper pages**, ...

# Post-Phillips Claim Construction

## ■ On Demand (con't)

### – **Summary of the Invention:**

- “It is therefore an object of the invention to provide a book manufacturing system which is capable of storing data corresponding to the text and color graphical cover of tens of thousands of different books, as well as promotional sales text and color graphics for aiding the consumer in choosing a book for purchase, and facilitate the high speed manufacture of a single copy of a selected book on the immediate premises while the customer waits for a very short time.”

# Post-Phillips Claim Construction

- On Demand (con't)
  - **Accused system prints and sells books as ordered by publishers, wholesalers, and retailers, but does not sell directly to retail consumers**
    - orders carry only identifying information, and system provides no promotional information
    - prints on rolls or webs of paper rather than on pre-cut sheets
    - Usually print in batches of 300+

# Post-Phillips Claim Construction

## ■ On Demand (con't)

- Jury: infringement and awarded \$15M damages
- DC: infringement
  - "sales information" = "data stored in a computer which is involved in the promoting and selling of a book," and that the term is not limited to promotional information, but includes descriptive information as well, such as price... of the book, Library of Congress notice, fly sheets, synopsis, plot outline, author's biographical summary, price, SKU and/or ISBN number.
  - "customer" = "who buys goods or services;" "customer" does not have to be an individual consumer or a retail customer.
  - "printing on paper pages" – may include printing on rolls that have to be cut
  - Preamble ("high speed manufacture of a single copy of a book") not limiting

# Post-Phillips Claim Construction

- On Demand (con't)
  - FC: Reversed
    - partly incorrect claim construction
    - on the correct construction a reasonable jury could not find the patent to be infringed (no promotional information)
    - “the court in Phillips...stressed the dominance of the specification in understanding the scope and defining the limits of the terms used in the claim.”

# Post-Phillips Claim Construction

## ■ On Demand (con't)

### – FC: Reversed

- “sale information” requires that promotional information is stored in the computer that is made available to the customer.; other identifying information alone cannot satisfy the “sales information” term
- “customer”
  - Although no disavowal of the standard dictionary meaning of “customer,” “when the scope of the invention is clearly stated in the specification, and is described as the advantage and distinction of the invention, it is not necessary to disavow explicitly a different scope. (quotes AstraZeneca; Bell Atlantic; and SciMed)
  - specification repeatedly reinforces its usage of the term “customer” as the retail consumer. and distinguishes “general purpose machines . . . not specifically designed to be consumer operated for the on demand, automatic manufacturing of a single book at the point of sale.”

# Post-Phillips Claim Construction

## ■ On Demand (con't)

### – FC: Reversed

- “printing on paper pages” = only printing on individual pages
  - “When this clause is correctly construed, no reasonable jury could find that it reads on a process of printing on large sheets or webs of paper that require the further processing step of cutting into pages after printing.”
- Preamble (“high speed manufacture of a single copy of a book”)
  - in this case, necessarily limits the claims in that it states the framework of the invention, “high speed manufacture of a single copy is fundamental to the Ross invention”
  - “the entirety of the claim implements the preamble's high speed manufacture of a single copy, upon customer review of the stored sales information, promptly printing and binding the single copy in response to the customer's selection. The preamble embraces the totality of these limitations, and limits the claim to the subject matter of the preamble.”<sup>53</sup>

# Post-Phillips Claim Construction

## ■ On Demand (con't)

- FC: "In Phillips, 415 F.3d at 1321, the en banc court explained that the role of the specification is to describe and enable the invention. In turn, the claims cannot be of broader scope than the invention that is set forth in the specification. Although we agree with the district court that the Ross invention does not concern itself with whether the "customer" reads the book or obtains it for resale, the focus of the Ross patent is immediate single-copy printing and binding initiated by the customer and conducted at the customer's site. The district court's definition of "customer" cannot eliminate these constraints in order to embrace the remote large-scale production of books for publishers and retailers."

# Post-Phillips Claim Construction

## ■ On Demand (con't)

- FC: “Although we agree with the district court that each term standing alone can be construed as having varying degrees of breadth, each term must be construed to implement the invention described in the specification. See Phillips, 415 F.3d at 1316 (Fed. Cir. 2005) ... Care must be taken lest word-by-word definition, removed from the context of the invention, leads to an overall result that departs significantly from the patented invention.”
- “the fundamental precept of the Ross invention is that the customer uses an on-site computer to view promotional information, and then initiates rapid single copy printing. A customer's placing an order with Amazon, who in turn obtains the book, even if it is printed in single copy, is not the Ross invention. Each of these components of the claimed invention is in the prior art; their combination is the patentable invention, and it is the practice of the combination that is essential to infringement.”
- “the direct customer role contemplated in the Ross patent... is central to the claim construction.”

# INEQUITABLE CONDUCT

## Principles and Basis for Inequitable Conduct

- Equitable principle that “he who comes into equity must come with clean hands.”  
Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co., 324 U.S. 806, 814 (1945)



# Duty of Disclosure Owed the USPTO

- **Who:** Everyone involved in drafting and prosecuting US patent application owes a duty of disclosure to the USPTO
  - 37 C.F.R. § 1.56: Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability[.]
  - M.P.E.P. § 2000
  
- **How far does the duty to disclose go?**
  - PTO has said that the standard of materiality covers more than just bases of examiner's decision to allow claims

## Duty of Disclosure Owed the USPTO

- Dayco Products, Inc. v. Total Containment, Inc., 66 U.S.P.Q.2d 1801 (Fed. Cir. 2003) (Dyk, Mayer, Michel)
- **Standard of materiality**
  - Before 1992: required a showing that “a *reasonable examiner* would have considered such prior art important in deciding whether to allow the parent application.”
    - 37 C.F.R. § 1.56(a) defined materiality using a “reasonable examiner” standard

## Duty of Disclosure Owed the USPTO

- Standard of Materiality (cont'd)
  - 1992 rule change
    - “not intended to constitute a significant substantive break in the previous standard.”
    - reiterated broad “duty of candor and good faith”
    - more narrowly defined materiality, providing for disclosure where the information establishes either “a prima facie case of unpatentability” or “refutes, or is inconsistent with a position the applicant takes.”
    - PTO: “clearer and more objective definition of what information the Office considers material to patentability”
- Dayco court didn’t decide what standard should apply when adjudicating issues of inequitable conduct

## Points to Keep in Mind

- Were all the experiments described performed?
- Are there experiments that were not included in the specification?
- Are there possible substitutes for variables that could be described?
- Are subjective evaluations presented as fact?
- Are assertions supported by science?

# EXAMPLES

- Hoffmann-LaRoche, Inc. v. Promega Corp., 323 F.3d 1354 (Fed. Cir. 2003) (NEWMAN, Archer, Bryson)
- A series of “unfortunate” representations
  - Example 6
    - Written in past tense but not performed as written
      - Originated from Preps 3 and 4; contained all steps but not same order as Example 6

# EXAMPLES

- Materiality: threshold level met
  - Response to office action: claimed product was more pure than prior art product
  - Product of Example 6 said to be highly pure
  - Examiner didn't principally rely on purity to allow claims
    - Though not focus, still important
    - Reasonable examiner would want to know no experimental results to support purity

# EXAMPLES

- Intent: threshold level met
  - Misrepresentations don't always equate with inequitable conduct
    - Must be intentional
  - Inventor knew past tense = actual work done
  - Roche provided no reason why past tense used for an experiment not performed
    - No evidence of oversight in use of past tense
  - No clear error in concluding use of past tense was knowingly false

# EXAMPLES

- Weighing of equities
  - Whether material misrepresentations in light of evidence of intent to deceive were sufficiently culpable to warrant holding of inequitable conduct
  - District Court didn't make such a finding
  - Remanded to determine if CAFC's findings of inequitable conduct justify sanction of unenforceability

# Assertions

- Purdue Pharma L.P. v. Endo Pharms., Inc., 438 F.3d 1123, 77 U.S.P.Q.2d 1767 (Fed. Cir. 2006)
  - Claim 1 of the '912 patent: “A controlled release oxycodone formulation for oral administration...”
  - Claim 1 of the '042 patent: “A method for reducing the range in daily dosages required to control pain...”
  - “Detailed Description” in each asserted patent:
    - “It has now been **surprisingly discovered** that the presently claimed controlled release oxycodone formulations acceptably control pain over a substantially narrower, approximately four-fold [range] (10 to 40 mg every 12 hours—around-the-clock dosing) in approximately 90% of patients. This is in sharp contrast to the approximately eight-fold range required for approximately 90% of patients for opioid analgesics in general.”

## Assertions: June 2005 CAFC Opinion

- In earlier Federal Circuit opinion, inequitable conduct found based on lack of support for statement in specification and prosecution history for properties of claimed invention
  - Although assertions written the past tense, it turned out that they were based on “insight” rather than scientific proof
    - Materiality: repeated statements that the discovered reduced dosage amount was based on insight without scientific proof
    - Intent: “clear pattern of intentional misrepresentation”
      - Consistent and repeated arguments during prosecution supports deliberate decision to withhold and mislead as to origin of “results”

## Assertions: February 2006 CAFC Opinion

- FC: "The thrust of this language is that the invented oxycodone formulation using a four-fold range of dosages (e.g., between 10 mg and 40 mg) achieves the same clinical results as the prior art opioid formulations using an eight-fold range of dosages (e.g., between 10 mg and 80 mg)."
- "clinical significance" -> more efficient titration process to provide acceptable pain relief without unacceptable side effects

# Assertions: District Court

- Purdue made repeated and convincing representations to the PTO that it had discovered its controlled release oxycodone formulations controlled pain over a four-fold range of dosages for 90% of patients, compared to an eight-fold range for other opioids.
- Purdue relied on its discovery as “a prominent, and at times, the only, argument in favor of patentability before the PTO, resulting in allowance of the claims.”
- **By failing to explain to the PTO that Dr. Kaiko’s “insight” provided the only support for its “discovery,” Purdue failed to disclose material information that was inconsistent with its arguments for patentability.**

# Assertions: February 2006 CAFC Opinion

- Upheld finding of materiality
  - “While Purdue never expressly stated that the discovery of the four-fold dosage range was based on the results of clinical studies, that conclusion was clearly to be inferred from the language used by Purdue in both the patents and prosecution history.”
    - neither the written description nor the pending claims of the ‘331 patent application made reference to the four-fold dosage range.
    - Used words like “result” and “clinical significance”
    - “In the absence of any statements indicating the true origin of its ‘surprising discovery,’ Purdue’s arguments to the PTO provide enough of a suggestion that clinical trials had been performed that failure to tell the PTO the discovery was based on Dr. Kaiko’s insight and not scientific proof was a failure to disclose material information.”
  - May be material without being basis of allowance
  - Material because result based on insight inconsistent with statements suggesting otherwise

# Assertions: February 2006 CAFC Opinion

- materiality “is not limited to matters reflected in the claims of a patent.”
- More than enthusiastic advocacy
  - distinguished CFMT, Inc. v. Yieldup International Corp., 349 F.3d 1333 (Fed. Cir. 2003)
  - “Purdue’s assertion of a four-fold dosage range for oxycodone and more efficient titration process compared to other opioids was ... one of the key arguments Purdue made consistently and repeatedly during prosecution to overcome prior art cited by the examiner in an obviousness rejection.”

## Assertions: February 2006 CAFC Opinion

- similar to Hoffmann-La Roche (erroneously stated that a procedure had been performed and presented “results” of that procedure
  - trial court’s finding not based on Purdue’s failure to provide scientific proof of its “surprising discovery,” but on repeated failure to tell PTO that the discovery based only on the inventor’s insight after suggesting during prosecution that the discovery was based on the results of clinical studies. .

## Assertions: February 2006 CAFC Opinion

- “While we affirm the trial court’s finding that Purdue’s actions met a threshold level of materiality, **we stress that the level of materiality is not especially high.** Purdue did not expressly misrepresent to the PTO that it had obtained experimental results establishing a four-fold dosage range for oxycodone, an act that likely would have been highly material. Instead, Purdue made statements implying that an empirical basis existed for its discovery and then failed to disclose that the discovery was based only on insight. This omission of information was material, but not as material as an affirmative misrepresentation would have been.
- trial court may have erred to the extent it relied on a high level of materiality in determining whether Purdue intended to deceive the PTO and whether Purdue ultimately committed inequitable conduct.

## Assertions: February 2006 CAFC Opinion

- "Intent to deceive, however, cannot be 'inferred solely from the fact that information was not disclosed; there must be a factual basis for a finding of deceptive intent.'"
- "'materiality does not presume intent, which is a separate and essential component of inequitable conduct.'"
- "In a case such as this, when the materiality of the undisclosed information is relatively low, there is less basis for inferring intent from materiality alone."

## Assertions: February 2006 CAFC Opinion

- “the quantum of proof necessary for FDA approval is significantly higher than that required by the PTO. *Therefore, evidence that Purdue personnel believed it would be difficult to satisfy FDA requirements is at best marginally related to whether they intended to deceive the PTO.* For these reasons, the trial court erred in giving the weight it did to this evidence when determining that Purdue acted with deceptive intent during prosecution of its patents.”

# Assertions: February 2006 CAFC Opinion

- Vacate and remand for trial court to reconsider intent
  - “In doing so, the trial court should rethink the relevance of the evidence relating to whether Purdue could prove that OxyContin<sup>®</sup> was the most easily titratable analgesic. If the trial court still finds that a threshold level of intent to deceive has been established, the court should reweigh its materiality and intent findings to determine whether the sanction of unenforceability due to inequitable conduct is warranted. In making this determination, the trial court should keep in mind that when the level of materiality is relatively low, the showing of intent must be proportionately higher.”

## No Inference of Intent from Omitting Data

- Kao Corp. v. Unilever United States, Inc., 441 F.3d 963 (Fed. Cir. 2006)
  - Invention: keratotic plug removing product
  - alleged inequitable conduct
    - Selective disclosure of test results in declaration
    - Basis for “unexpected results” to overcome p.f. case of obviousness
    - did not disclose the margins of error for the tests
  - DC: Kao's patent valid and enforceable but not infringed
  - FC: Affirmed

# No Inference of Intent from Omitting Data

- Kao (con't)
  - DC: omission material, but not made with intent to deceive
    - Omitted data (but not margins of error) eventually disclosed
  - FC: review only for abuse of that discretion and underlying factual determinations for clear error
    - No abuse of discretion
    - "Intent to deceive 'cannot be inferred solely from the fact that information was not disclosed; there must be a factual basis for a finding of deceptive intent.' *Purdue Pharma*, 438 F.3d at 1134."
    - reluctant to question the judgment of the finder of fact, despite "glaring failure of the inventors to offer any rationale for the omission"
    - "Given a blank slate, we might weigh the evidence differently. Given the limited scope of our review, however, we cannot second-guess the trial court's decision."

# "AFFIRMATIVE MISREPRESENTATION"

- Atofina v. Great Lakes Chemical Corp.,  
441 F.3d 991 (Fed. Cir. 2006)
  - DC: patent unenforceable
    - fully translated version of JP 51-82206 not submitted to the PTO
      - Highly material "because it anticipate[d] all the limitations of claims
      - Intent to deceive the PTO inferred from fact that p'ee had translation in its possession
        - Failed to mention some of details of JP disclosure

# "AFFIRMATIVE MISREPRESENTATION"

## ■ Atofina (con't)

– FC: Reversed. District court abused its discretion

- "applicants' failure to disclose the full English translation is not in and of itself enough to infer intent, even if the full English translation went beyond the Derwent Abstract, which is far from clear."
- applicants' statements characterizing reference consistent with both the full English translation and the Derwent Abstract -> no support for an inference of intent
- reverse on intent

## Knowledge of the law imputed to the inventor

- Novo Nordisk Pharmaceuticals, Inc. v. Bio-Technology General Corp., 424 F.3d 1347 (Fed. Cir. 2005)
  - Intervening prior art
  - Novo claimed benefit of Danish priority document to avoid prior art, relying on Example 1 of the priority document support claims
    - Claimed invention: process for producing human growth hormone (hGH)
  - Example 1
    - Directed to the production of “ripe” hGH through the use of LAP enzyme

## Knowledge of the law imputed to the inventor

- Example 1 (cont'd)
  - Written in past tense
  - Work never performed
  - At time of filing, inventors had not successfully made hHG recombinantly
  - After filing, serendipitously made hGH using LAP from manufacturer that had a contaminate (discovered contaminant later; not in example)
- In interference on application in chain, relied on Example 1 for priority of count
  - Offered expert testimony re enablement of Ex. 1
- In patent-in-suit, inventor participated in examiner interview re enabling disclosure of Example 1 to support claim for benefit and avoid prior art
- Examiner awarded patentee claim to benefit and allowed application

## Knowledge of the law imputed to the inventor

- Materiality: FC agreed with DC
  - Examiner relied on Example for granting priority benefit and allowing application
  - Patentee didn't inform examiner either 1) that example not performed and results predicted, and 2) that applicant failed to make the example work as written
  - The examiner would have considered it important to know that the prophetic nature of the example and the fact that inventors could make it work
  - Same applied to representations made in the interference re Example 1

## Knowledge of the law imputed to the inventor

- Intent: FC found no clear error in DC's holding
  - More than nine years after it submitted Ex. 1, Novo *knew or should have known* that the examiner would have considered the prophetic nature of the example important in deciding whether Example 1 enabled the claims of the patent-in-suit, particularly since Novo could not successfully produce hGH following Example 1
  - Novo argued no intent because inventors not sophisticated enough to know that unperformed examples shouldn't be written in past, and the attorneys didn't know example wasn't performed

## Knowledge of the law imputed to the inventor

- Intent (cont'd)
  - FC rejected circular logic of Novo's position
  - Inventors knew Example 1 was prophetic and that they had not successfully produced hGH using the method of the example
  - Inventor attended the interview with Novo's attorneys where the enabling nature of example 1 discussed
  - Thus, knowledge of the law chargeable to inventor, especially when represented by counsel

## Take Away

- ✓ Review how examples are written and supported
- ✓ Review basis for factual representations made to the PTO
- ✓ Review test results

# CONNECTIONS BETWEEN DECLARANTS AND ASSIGNEE

- Ferring B.V. v. Barr Labs., Inc., --F.3d--, No. 05-1284 (Fed. Cir. February 15, 2006)
  - DC: SJ unenforceable due to inequitable conduct
  - FC: Affirmed
    - Patentee failed to disclose that “four of the five declarations submitted to the PTO ... were written by scientists who had been employed or had received research funds from Ferring”
    - Patentee knew Examiner wanted a non-inventor declaration

# CONNECTIONS BETWEEN DECLARANTS AND ASSIGNEE

## ■ Ferring (con't)

- Declarations material -> overcame obviousness rejection
- Intent to deceive -> inventor knew of connections, knew of the materiality of the declarations, no credible explanation for failure to disclose
- “where the objectivity of the declarant is an issue in the prosecution, the inventor must disclose the known relationships and affiliations of the declarants so that those interests can be considered in weighing the declarations. This is not an onerous burden to place on any applicant.”

# The End

*Thank you for your attention.*

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