

Patent Law

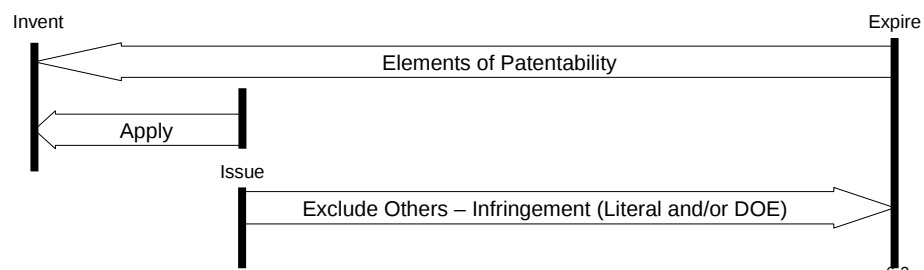
- Slides for Module 6
- The specification – objective disclosure & best mode

The elements of Patentability

- **Patentable subject matter**, i.e., patent eligibility
- **Useful/utility** (operable and provides a tangible benefit)
- **New** (statutory bar, novelty, anticipation)
- **Nonobvious** (not readily within the ordinary skills of a competent artisan at the time the invention was made)
- **Specification requirements** (enablement, written description, best mode, definiteness)



"Reading" a claim onto prior art	Validity
"Reading" a claim onto its own specification	First step regarding §112
"Reading" a claim onto accused device or process	Infringement



Specification Requirements

- Enablement is the central doctrine
 - It fulfills the "public disclosure" part of the patent bargain
 - It helps delimit the boundaries of patent protection by ensuring that the scope of a patent claim accords with the extent of the inventor's technical contribution
- Written description doctrine is in flux
 - Ordinarily operates to police priority when inventors amend their disclosures
 - New claims or new subject matter must be supported by the originally filed specification
 - Recent cases have applied the written description test as a more stand-alone requirement

§ 112 ¶¶1-2 Language

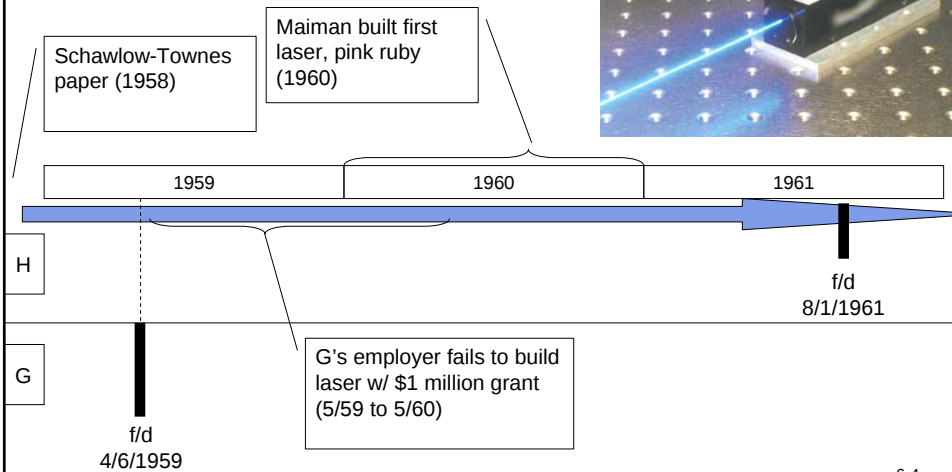
[¶1] The specification shall contain a written description of the invention, and of the <u>manner and process of making and using it</u> , in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to <u>make and use</u> the same,	Written Description requirement. Enablement requirement.
and shall set forth the best mode contemplated by the inventor of carrying out his invention.	Best Mode requirement.
[¶2] The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.	Definiteness requirement.

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Gould v. Hellwarth (CCPA 1973) (Lane, J.)

- Enablement to make
- There is more to the priority race than just being first . . .
- Same Gould as in Gould v. Schawlow (CCPA 1966) (diligence case)



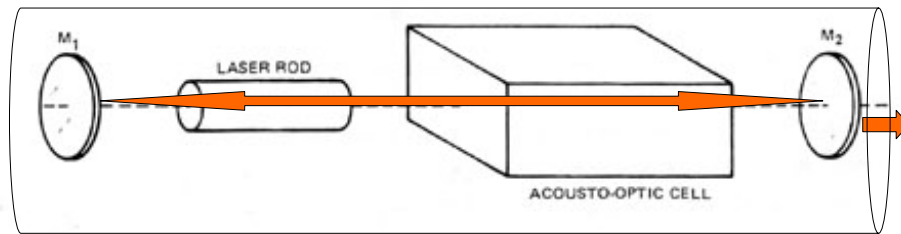
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Gould v. Hellwarth (CCPA 1973) (Lane, J.)

- Subject of the counts (paraphrased)
 - “optical maser”
 - laser material (the lasing medium that is “pumped” with energy to produce an inversion)
 - means for pumping the material to a condition of stimulated emission (this means is usually a light or radiation source) [not shown below], and
 - reflecting means defining a radiation path in the material for repeatedly reflecting the stimulated emission energy radiated by the material between the reflecting means
 - altering means to change the amount of stimulated energy reflected by the reflecting means
 - “altering means” allows buildup of energy for a “giant pulse”
 - Called Q-switched because the altering means vary the electrical quality of “Q” of the “cavity” in which the working material is confined



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Gould v. Hellwarth (CCPA 1973) (Lane, J.)

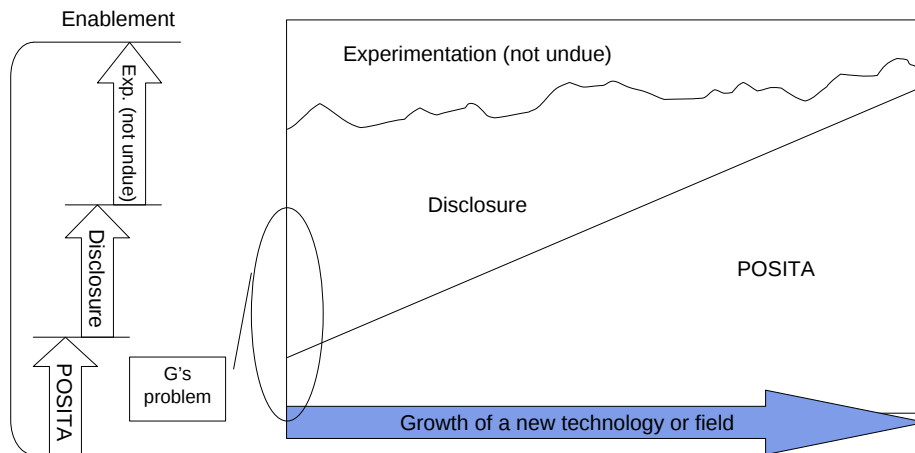
- H's expert Lengyel testified
 - As of 1959, the G disclosure did not have sufficient information for a POSITA to build an operative laser of any kind
 - One needs to know properties of the lasing material, temperature ranges, gas pressures, relational dimensions, minimum radiation necessary for excitation, discharge properties, properties of the cavity, reflectivity and curvature of the mirrors, etc.
 - G's disclosure shows details for various lasers, but does not disclose a complete set of operating parameters for any laser
 - The PTO and the Court took G's experts (Bloom & Fowles) to be in substantial agreement with Lengyel on these three points
 - It did not matter that Bloom & Fowles also testified that in their opinion the invention was enabled by G's 1959 disclosure
 - Their agreement with Lengyel on the three points above is inconsistent with their enablement opinion
- G's disclosure, painted in its best light, was insufficient
 - Sodium-mercury lasing medium disclosure is not sufficient – as of 1968 this medium has not been shown to work
 - Disclosure's listing of ruby (generally) as alternative material is insufficient
 - Maiman had to investigate hard to understand that pink ruby, not regular ruby, worked

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Gould v. Hellwarth (CCPA 1973) (Lane, J.)



- POSITA knowledge is likely to go up over time in a nascent field
- But, various factors will determine tradeoff between disclosure and undue experimentation
 - Field of the art, complexity of the invention, unpredictability of the technology

Enablement – other points

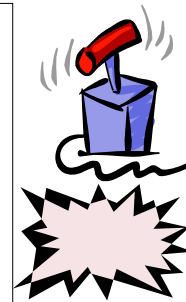
- Enablement does not require disclosure of how to mass produce
 - Federal Circuit - Christianson v. Colt (Fed. Cir. 1987)
 - patent is not a production document
 - It does not need to disclose data to mass produce
- Other
 - Repetition required?
 - Deposits
 - Scientific truths?

Enablement – other points

- In a patent for a method of producing a protein, there was a reference in a step to “cleaving a conjugate protein”
 - commonly called “cleavable fusion expression” – but required some details to be workable
 - The defendant asserted that the patent was not enabling w/ only a mere statement of the possibility of cleaving
 - Federal Circuit - Genentech v. Novo (Fed. Cir. 1997)
 - Enablement is not vague intimations of general ideas that may or may not be workable
 - Mere germ of an idea is not enablement
 - Need reasonable detail to enable
 - Where there is no disclosure of any specific (i) process, (ii) starting material or (iii) any of the conditions under which a process can be carried out, undue experimentation **is required**
 - It is the specification, not the POSITA knowledge, that **must supply the novel aspects** of an invention in order to constitute adequate enablement

Atlas Powder v. Dupont (Fed. Cir. 1984) (Baldwin, J.)

- Claim 1
- 1. An emulsion blasting agent **consisting essentially of**:
 - an aqueous solution of ammonium nitrate forming a discontinuous emulsion phase [small globules of explosive];
 - a carbonaceous fuel forming a continuous emulsion phase [the second liquid, an oil, in which the small globules are suspended];
 - an occluded gas dispersed within said emulsion and comprising at least 4% by volume, thereof at 70 degrees F. and atmospheric pressure [the entrapped air that sensitizes the blasting characteristic of the product]; and
 - a water-in-oil type emulsifying agent;
 - said carbonaceous fuel having a consistency such that said occluded gas is held in said emulsion at a temperature of 70 degrees F.



- **e-mul-sion** - A suspension of small globules of one liquid in a second liquid with which the first will not mix

Atlas Powder v. Dupont – an aside for transitional phrases



Type	Words	Meaning / Notes
Open	comprising Also: including containing characterized by	“having at least” The most common and desirable Does not exclude additional, unrecited elements or method steps
Closed	consisting of	“having only” Closes the claim to the inclusion of other elements (except impurities)
Partially closed	consisting essentially of	“having nothing else that affects operation” Limits the scope of the claim to the specified elements “and those that that do not materially affect the basic and novel characteristics”

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Atlas Powder v. Dupont – Undue Experimentation



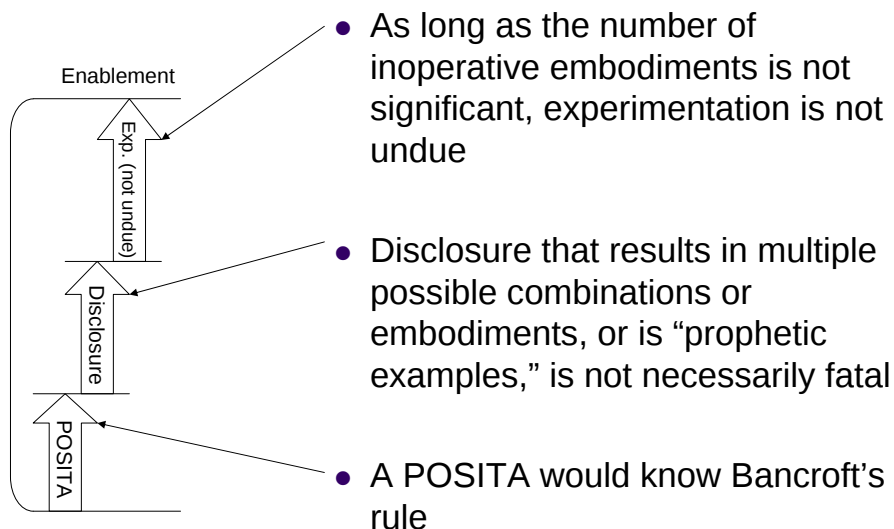
- Dupont asserts
 - the disclosure lists numerous salts, fuels, and emulsifiers that could form thousands of emulsions
 - but no commensurate teaching as to which combination would work
 - There are inoperative embodiments in the combinations arising from the disclosed lists
 - Of 300 Atlas experiments, 40% “failed”
 - Only 2 of the listed emulsifiers worked, so construe claims to cover only these two
- The court did not buy this attack
 - A POSITA would know how to apply Bancroft’s rule – a basic principle of emulsion chemistry – to select from the disclosed lists and create the emulsion
 - Bancroft’s rule - Emulsion Stability Is Favored By Solubility In The Continuous Phase
 - The experiments were not failures, just not optimum under all conditions

Atlas Powder v. Dupont – Undue Experimentation



- Claims are not necessarily invalid when there are inoperative combinations
 - As long as the number of inoperative embodiments is not **significant**, such that required experimentation becomes undue, then enablement is not defeated
- Prophetic examples are not automatically invalidating
 - Challenger needs to prove invalidity due to nonenablement with CCE
 - The disclosed examples are from specific experiments, slightly modified to be optimum, to facilitate enablement

Atlas Powder v. Dupont



In re Wright (Fed. Cir. 1993) (Rich, J.)

- Claim 1 (rejected by examiner)
 - A process for producing a live non-pathogenic vaccine for a pathogenic RNA virus, comprising the steps of identifying the antigenic and pathogenic gene regions of said virus; performing gene alteration to produce a genome which codes for the antigenicity of the virus, but does not have its pathogenicity; and obtaining an expression of the gene.
- Claim 13 (allowed – specific to the sole example in Wright's application)
 - A live, non-pathogenic vaccine for a pathogenic RNA virus, comprising an immunologically effective amount of a viral, antigenic, genomic expression having an antigenic determinant region of the RNA virus, but no pathogenic properties, the viral, antigenic, genomic expression being the RAV-Acn virus.
- Terms
 - Pathogenic = disease causing
 - Antigenic = antibody producing
- Bottom line policy inquiry for this enablement issue
 - What in the disclosure, with only one example, assures the public that this method will create nonpathogenic vaccines against “any and all” RNA viruses when such viruses are a large, diverse and complex class?

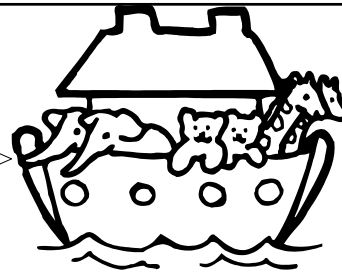


In re Wright



Work for all other animals?

Work for other birds?



- Wright's specification contains only one working example
 - for chickens
- Are his claims to use of the method in all other animals enabled?
 - What about his alternative argument that the claim is at least enabled for other birds?



In re Wright



● Holding

- As examiner & Board noted, these are vaccines – which must by definition trigger an immunoprotective response
 - mere antigenic response is not enough
- Claim goes to any and all non-pathogenic vaccines to RNA viruses in any animal
 - Would cover AIDS viruses, which have not yet proven workable.
 - Wright says some (of his) SIV and HIV vaccines have shown promise in animal models, so there is no undue experimentation because the technology is not as unpredictable as thought
 - The Court rejects this argument – such activity is **after Wright's filing date**

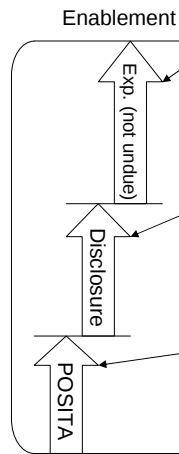
In re Wright



● Holding (cont'd)

- Wright argues that the method will work for other birds, even if not for humans or other animals
 - Court says that Wright has not carried his burden on this
 - Wright has the burden on enablement because the PTO set forth a reasonable basis for finding the claims not enabled
 - Wright himself discussed the need for in vivo testing:
 - Preparation of a patent application following conception of the invention awaited such time as there was a reasonable expectation that the results of inoculation [sic] would be successful. *This became apparent only by reason of survival of the chickens that had been inoculated [sic].*
 - Wright says this was just hypothesis testing
 - Once hypothesis is formed and proven, a POSITA could later apply the method to other birds
 - But, in a 1985 paper co-authored by Wright, he suggests that genetic diversity among chickens alone required efficacy testing

In re Wright



- Wright himself had to expend extensive effort to obtain success with the chicken example
- As to claim 1, only one example for a method that applies to any RNA virus in any animal
- In 1983, POSITA knowledge does not include what is required to implement Wright's method with a reasonable expectation of success on any RNA virus in any animal

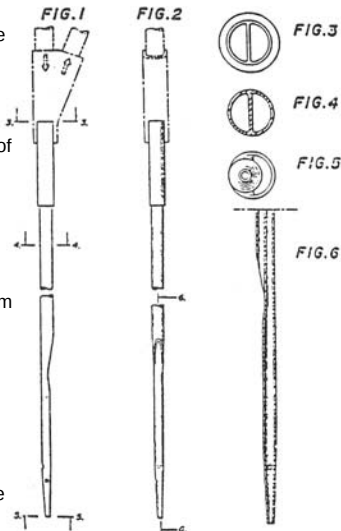
Enablement – undue experimentation – Wands factors

- quantity of experimentation necessary
- amount of direction or guidance provided
- presence or absence of working examples
- nature of the invention
- state of the prior art
- relative skill of those in the art
- predictability or unpredictability of the art
- the breadth of the claims

Vas-Cath v. Mahurkar (Fed. Cir. 1991) (Rich, J.)

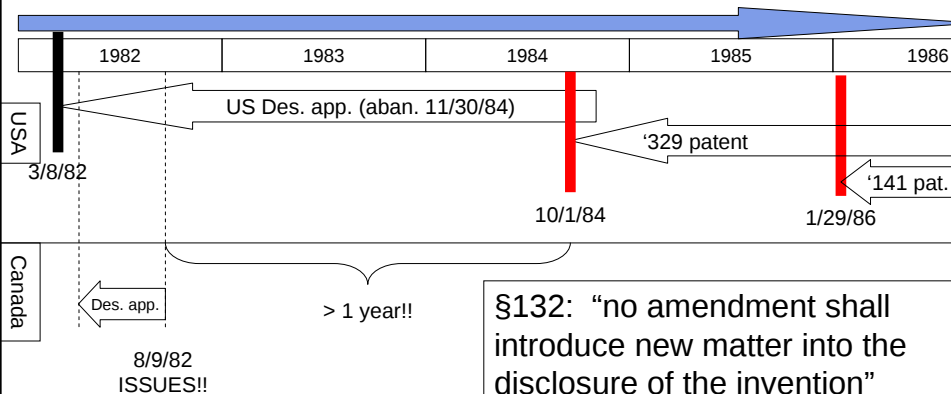
- 7. A double lumen catheter having an elongated tube with a proximal first cylindrical portion enclosing first and second lumens separated by an internal divider, the proximal end of said elongated tube connecting to two separate connecting tubes communicating with the respective first and second lumens for the injection and removal of fluid, the first lumen extending from the proximal end of said elongated tube to a first opening at the distal end of said elongated tube, and the second lumen extending from the proximal end of said elongated tube to a second opening at approximately the distal end of said first cylindrical portion, wherein the **improvement comprises:**

- said elongated tube having at its distal end a smooth conical tapered tip that smoothly merges with a second cylindrical portion of said elongated tube,
- and said second cylindrical portion enclosing the first lumen from the conical tapered tip to approximately the location of said second opening, said second cylindrical portion having a diameter substantially greater than one-half but substantially less than a full diameter of said first cylindrical portion,
- said divider in said first cylindrical portion being planar,
- the lumens being "D" shaped in cross-section in said first cylindrical portion,
- the elongated tube being provided with a plurality of holes in the region of the conical tapered tip, and
- said first cylindrical portion of the elongated tube smoothly merging with said second cylindrical portion of the elongated tube.



Vas-Cath v. Mahurkar (Fed. Cir. 1991) (Rich, J.)

- Ultimate effective f/d for Mahurkar's two utility patents on the catheter is based on priority [red bars] from a design patent application
 - Design patent applications consist almost exclusively of the drawings
 - Only a short "claim" is included:
 - "The ornamental design for a _____, as shown [and described]."
- How does this raise a §112 ¶1 Written Description issue?



Vas-Cath v. Mahurkar (Fed. Cir. 1991) (Rich, J.)

- Written description comes up for
 - later filed claims
 - continuations under §119 [provisional] or §120 [non-provisional]
- Include drawings?
 - Written word, i.e., language, or
 - human-made marks or symbols recorded in the application?
- Written description versus §112 ¶2 “definiteness” requirement
 - Doesn’t “definiteness” imply a “written description”
 - Different purposes
 - definiteness puts public on notice of claim scope
 - Written description “guards against the inventor’s overreaching” in future added claims

Vas-Cath v. Mahurkar (Fed. Cir. 1991) (Rich, J.)

- Written description versus §112 ¶1 enablement requirement
 - Possible to enable but not describe
 - But, it is also possible to describe but not enable (example – chemical formula)
 - Outside of “policing” new matter – are these distinctions worth much?
- Formulation of the traditional “new matter policing” written description test
 - the applicant must also convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was ***in possession of the invention***. The invention is, for purposes of the “written description” inquiry, *whatever is now claimed*.
- Outcome of present case?

Written description – genus / species

- It has specifically been held that the disclosure of a genus and a species of a subgenus within that genus
- **is not**
- sufficient description of the subgenus to comply with the description requirement of 35 U.S.C. 112,
- **unless**
- there are specific facts which lead to a determination that a subgenus is implicitly described

Written Description Debate – Enzo Biochem v. Gen-Probe (Fed. Cir. 2002)

§ 112 ¶1 Language

[¶1] The specification shall contain a **written description** of the invention, and 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,

Written Description requirement.

Enablement requirement.

- US Brief as amicus curiae in support of rehearing en banc
 - This court rejected the "straightforward reading" of the statute in *Vas-Cath* because the written description (WD) doctrine was a priority control, not the general disclosure doctrine of enablement. . . . Within the proper purpose of WD, *Vas-Cath* makes sense. When applied outside the priority context as a general disclosure doctrine, however, WD cannot depart from the enablement test without replacing it. Thus, the United States advocates application of the statutory standard of enablement

Written Description Debate – <u>Enzo Biochem v. Gen-Probe</u> (Fed. Cir. 2002)	
§ 112 ¶1 Language	
[¶1] The specification shall contain a written description of the invention, and 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,	Written Description requirement. Enablement requirement.
• Written description applied to claims without new matter problems – is this a “super-enablement” requirement? • From the majority who voted to not hear <u>Enzo</u> en banc • “The dissenters believe that the written description requirement is simply a requirement for enablement. With all due respect, that is incorrect. The <i>complete</i> statutory provision is as follows . . . note the comma . . . and the “and” . . . • Statute does not say a “written description . . . [to] police priority” • How do you read the statute?	
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Written Description Debate – <u>Enzo Biochem v. Gen-Probe</u> (Fed. Cir. 2002)	
§ 112 ¶1 Language	
[¶1] The specification shall contain a written description of the invention, and 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,	Written Description requirement. Enablement requirement.
• The <u>Enzo</u> standard • “[when] gene material has been defined only by a statement of function or result . . . such a statement alone [does] not adequately describe the claimed invention” unless the • <i>functional characteristics [are] coupled with a known or disclosed correlation between function and structure</i> • “an adequate written description of genetic material requires a precise definition, such as by structure, formula, chemical name, or physical properties, not a mere wish or plan for obtaining the claimed chemical invention” • “The disclosure must allow one skilled in the art to visualize or recognize the identity of the subject matter purportedly described”	
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Written Description Debate – Enzo Biochem v. Gen-Probe (Fed. Cir. 2002)

§ 112 ¶1 Language

[¶1] The specification shall contain a **written description** of the invention, **and** 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,

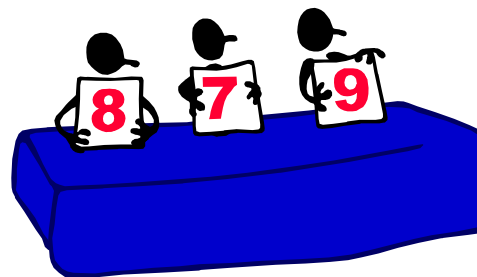
Written Description requirement.

Enablement requirement.

- The Enzo standard (cont'd)
 - Application of the written description requirement, however, is not subsumed by the "possession" inquiry. A showing of "possession" is ancillary to the *statutory* mandate that "[t]he specification shall contain a written description of the invention," and that requirement is not met if, despite a showing of possession, the specification does not adequately describe the claimed invention.
- Where does that leave patent law?

Univ. of Rochester v. G.D. Searle and Co., Inc., 03-1304o (Fed. Cir. July 2, 2004)

- Clarification for the issue?



Objective Disclosure Exercise

- Rameau is an inventor and licensed United States patent agent. Late in the evening on December 31, 1997, he conceives of the idea of an improved champagne corkscrew. He subsequently prepares a sales brochure with a detailed and complete description of the new corkscrew for distribution at a regional wine festival held in Napa, California, on September 10, 1998.
- Two days before the festival, Rameau considers whether he should file a patent application on the corkscrew. Although 35 U.S.C. § 102(b) provides him with a one year grace period in the United States, he recalls that most foreign patent systems are absolute novelty regimes. Distribution of the sales brochures could thus be fatal to Rameau's potential patent rights elsewhere. Rameau hastily drafts an application that evening and files it at the United States Patent and Trademark Office the next day, on September 9, 1998.
- At the festival, Rameau distributes over 1500 brochures to prospective customers. A few days later, Rameau reviews his patent application and realizes that he did not describe grasping arms which seize the champagne stopper, a key feature of the invention that the sales brochure detailed. Rameau very much doubts that skilled workers in the field could make or use his invention without this additional information.
- How may Rameau modify his patent specification in order to meet § 112, first paragraph? Does Rameau possess any other options in order to fulfill the requirements of § 112, first paragraph?

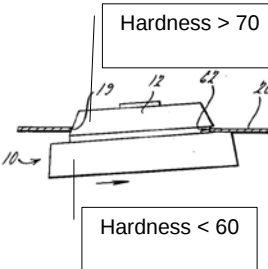
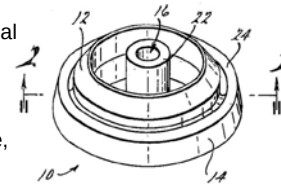


Best Mode

- The specification “shall set forth the best mode contemplated by the inventor of carrying out his invention”
- This requires disclosure in the patent specification of any specific instrumentalities or techniques that the inventor recognized at the time of filing as the best way of carrying out the invention
- Thus, the specification must disclose at least some of the inventor’s trade secrets for practicing the invention

Best Mode - Chemcast v. Arco (Fed. Cir. 1990) (Mayer, J.)

- 1. A grommet for sealing an opening in a panel, said grommet comprising
 - an annular base portion [14] having a continuous circumferential and axial extending sealing band surface,
 - an **annular locking portion** [12] having a continuous circumferential and axial extending ridge portion approximately the same diameter as said sealing band surface,
 - said sealing band surface constituting an axial extending continuation of said ridge portion,
 - said locking portion and said base portion being in contact with each other and integrally bonded together,
 - said base portion comprising an elastomeric material and said **locking portion being more rigid than said base portion**,
 - whereby when the grommet is installed in a panel opening, the locking portion is inserted through the opening to a position on the opposite side of the panel from the base portion locking the grommet in place, and said sealing band surface forms a complete seal continuously around the entire inner periphery of the panel opening.
- 6. The grommet as defined in claim 1 wherein the material forming said base portion has a durometer hardness reading of less than 60 Shore A and the material forming said locking portion has a durometer hardness reading of more than 70 Shore A.



Best Mode - Chemcast v. Arco (Fed. Cir. 1990) (Mayer, J.)

- District Court
 - claim 6 is invalid due to failure to disclose best mode
 - Specifically due to failure to specify
 - the particular type
 - hardness and
 - supplier and trade name of the material used to make the locking portion of the grommet

Best Mode - Chemcast v. Arco (Fed. Cir. 1990) (Mayer, J.)

- The disclosure from the patent
 - The annular locking portion 12 of the sealing member 10 is preferably comprised of a rigid castable material, such as a castable resinous material, either a thermoplastic or thermosetting resin, or any mixtures thereof, for example, polyurethane or polyvinyl chloride. The portion 12 also should be made of a material that is sufficiently hard and rigid so that it cannot be radially compressed, such as when it is inserted in the opening 19 in the panel 20. ***Materials having a durometer hardness reading of 70 Shore A or harder are suitable in this regard.***

Best Mode - Chemcast v. Arco (Fed. Cir. 1990) (Mayer, J.)

- “The [durometer] standard covers type A, B, C, D, DO and OO durometers. The most popular durometers are types A and D. Type A is often used for rubber and soft plastics while type D is used for harder materials such as bowling balls and thermo plastics”



Best Mode - Chemcast v. Arco (Fed. Cir. 1990) (Mayer, J.)

- Federal Circuit – two step Best Mode inquiry – each step having two elements
 - The inventor’s state of mind at the time she filed her application
 - a subjective, factual question
 - First
 - Ask whether the inventor ***knew of a mode of practicing the invention that he or she considered to be better than any other***
 - Applies even if the inventor did not originate that mode
 - Second
 - If the inventor in fact contemplated such a preferred mode, did the inventor ***conceal that best mode by not disclosing it***
 - Unless the filing is a continuation application, in which case there is no requirement to update the disclosure
 - If so, evaluate the second step
 - But note, not every preference is a “best mode”

Best Mode - Chemcast v. Arco (Fed. Cir. 1990) (Mayer, J.)

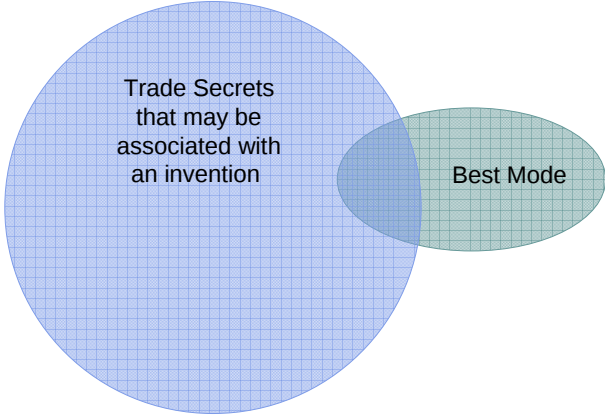
- Federal Circuit – two step Best Mode inquiry
 - Compare what the inventor knew with what she disclosed
 - Two objective elements to the second step
 - First
 - The disclosed best mode must be understandable to a POSITA
 - This is a question of the sufficiency of the disclosure concerning the mode that the inventor thought was best
 - Ask how a POSITA would have understood the disclosure
 - Second
 - Compare to the scope of the claims – does the nondisclosed best mode fall
 - ***within the claim scope***
 - or
 - ***does it materially affect the properties of the claimed invention itself?***
 - ***[NOTE – this is recently articulated and somewhat disputed “expansion” as to what the best mode requirement covers]***
 - Traditionally, there has been no requirement to disclose the “best mode” of something not within the scope of the claims, although this rule is easier to state than apply

Best Mode - <u>Chemcast v. Arco</u> (Fed. Cir. 1990) (Mayer, J.)		
Element	Chemcast	Fed. Cir.
Subjective	Even if Rubright had a "best mode" there was no concealment of it	13 findings by district court make for a compelling factual record - broad description in specification of locking material, yet Rubright used a specifically developed and trade-name identified material, R-4467 - only one embodiment - different hardness measurement, "Shore D" when claim recites "Shore A" - Rubright did not know himself the formula, composition or method of manufacture of R-4667, so this obligates him to disclose supplier and trade name
Objective		
- claim scope?	No material claimed in claim 6 for locking portion	Chemcast confused best mode w/ enablement - broad claim, but preferred material is an embodiment within the scope of the claims - claim specifies some attributes of the locking portion material, such as durometer hardness
- how would POSITA take the disclosure?	Given POSITA skill, best mode is implicitly disclosed	Confuses enablement with best mode - given the different hardness measuring scales, a POSITA would not take the specification as having disclosed the preferred embodiment
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Best Mode - Chemcast v. Arco (Fed. Cir. 1990) (Mayer, J.)




Who is the "inventor" for purposes of best mode?



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