

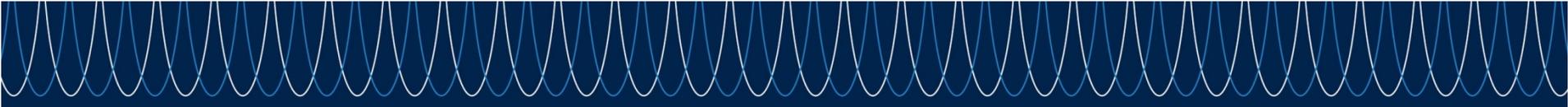


# Sufficiency of Disclosure

## What the U.S. Requires Beyond EPC Article 83, Even in Priority Applications

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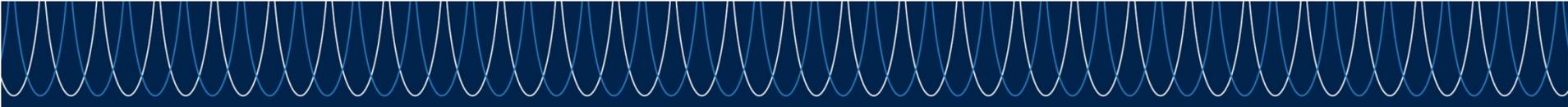




# U.S. Equivalent of EPC Article 83

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, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

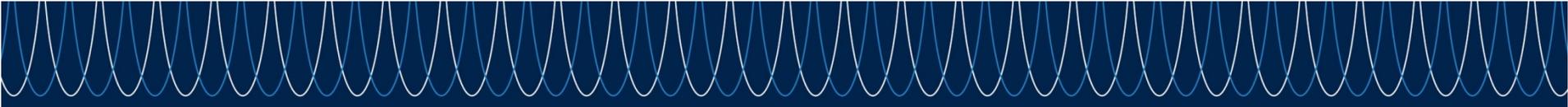
35 U.S.C. § 112, paragraph 1



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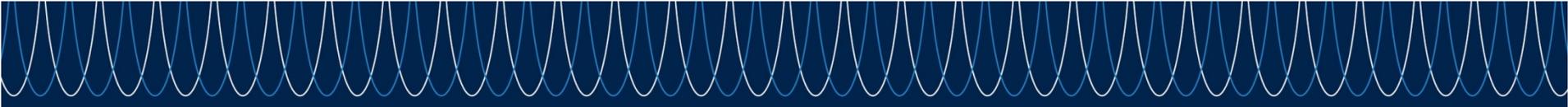
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# Foreign Documents Must Comply with § 112 for Valid Priority

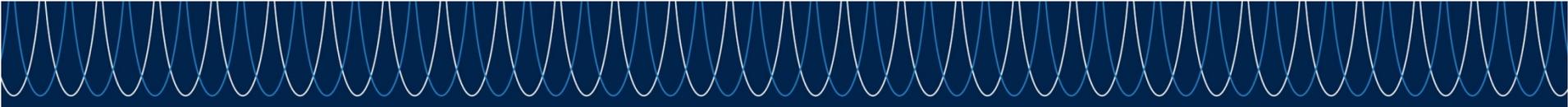
“Section 119 provides that a foreign application ‘shall have the same effect’ as if it had been filed in the United States. 35 U.S.C. § 119. Accordingly, ... **the foreign priority application must be examined to ascertain if it supports, within the meaning of section 112, ¶ 1, what is claimed in the United States application.**”

*In re Gosteli*, 872 F.2d 1008 (Fed. Cir. 1989)



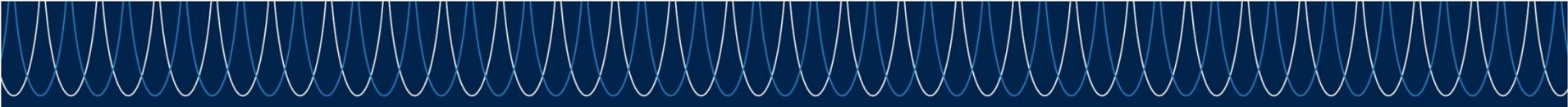
## Written Description

The specification must convey to a person of ordinary skill that the inventor(s) *had invented* (per some cases) or *had possession of* (per other cases) the claimed invention as of the claimed priority date.



# “The Invention” means:

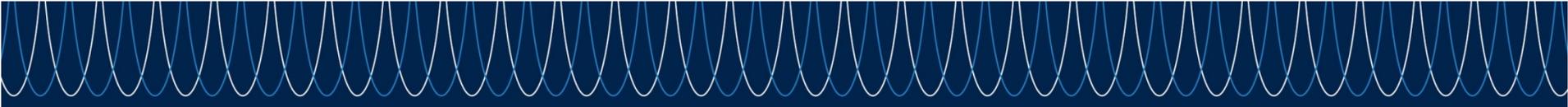
- ❖ Amended or new claims
- ❖ Claims for which an earlier priority date is asserted
- ❖ Support for a count in an interference
- ❖ Originally filed claims



# Written Description – Multiple Factors to Consider

- ❖ Nature of the invention at issue
- ❖ Predictability of the aspect at issue
- ❖ Scope of the invention
- ❖ Other considerations appropriate to the subject matter
- ❖ Existing knowledge in the particular field, the extent and content of the prior art
- ❖ Maturity of the science or technology

*Capon v. Eshhar* (CAFC 2005)



## Written Description ≠ Literal Support

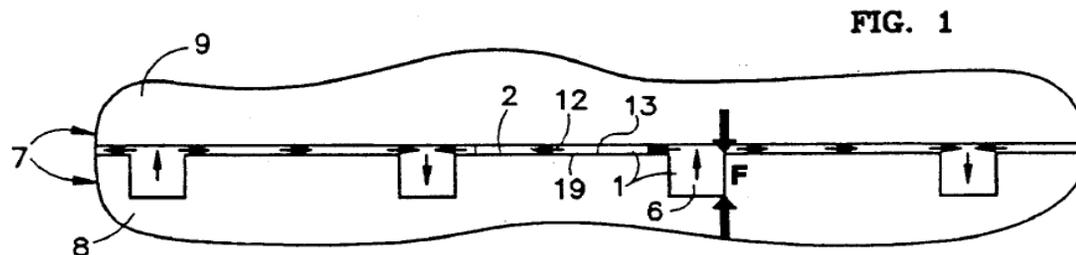
“The test ... is whether the disclosure of the application as originally filed *reasonably conveys* to the artisan that the inventor *had possession* at that time of the later claimed subject matter, **rather than the presence or absence of literal support in the specification for the claim language.** ... The content of the drawings may also be considered ...”

*In re Kaslow*, 707 F.2d 1366, 217 USPQ 1089 (Fed. Cir. 1983)

# Examples of Adequate Description

## *Koito Manufacturing*

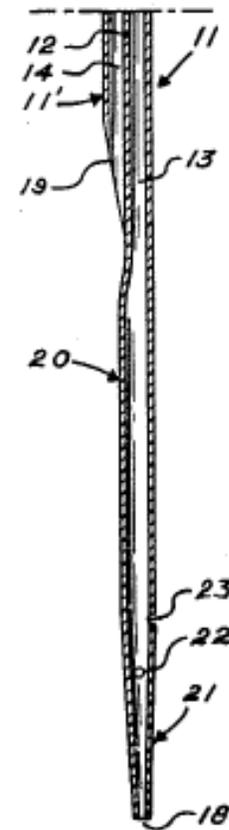
- ❖ The patent specification provided adequate support in its Figure 1 for a claim limitation that a flow channel be “significantly thicker and wider” than the adjacent cavity thickness.
- ❖ Written description requirement may be satisfied by “words, structures, figures, diagrams, formulas, etc.”

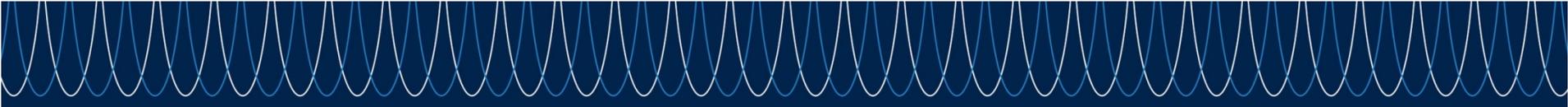


# Examples of Adequate Description

## *Vas-Cath*

- FR A priority **design** patent application with drawings depicting a catheter provided a sufficient “description of the invention” to support a later **utility** patent application’s catheter claims.
- FR “Under proper circumstances, drawings alone may provide a ‘written description’ of an invention as required by §112.”





# Examples of Inadequate Description

## *Chiron Corp.*

- ❖ CIP filed in 1995 (issued as patent) claimed priority to 1984, 1985, and 1986 applications.
- ❖ District court interpreted broad claims to monoclonal antibodies to “embrace not only murine antibodies but also chimeric and humanized antibodies.”
- ❖ Since chimeric antibody technology did not exist at the time of the 1984 filing, that application cannot have provided written description support for the claims of the patent.

**Written description sufficiency is determined with respect to the entire scope of the claims.**

# Examples of Inadequate Description

## *In re Wilder*

- ❖ Reissue patent attempted to broaden claims to dictating machine to remove requirement for synchronous scanning.
- ❖ Only disclosed embodiment synchronously scanned.
- ❖ Court found no evidence that the inventors had possession of the broader invention.
- ❖ Other cases come out differently on similar facts.

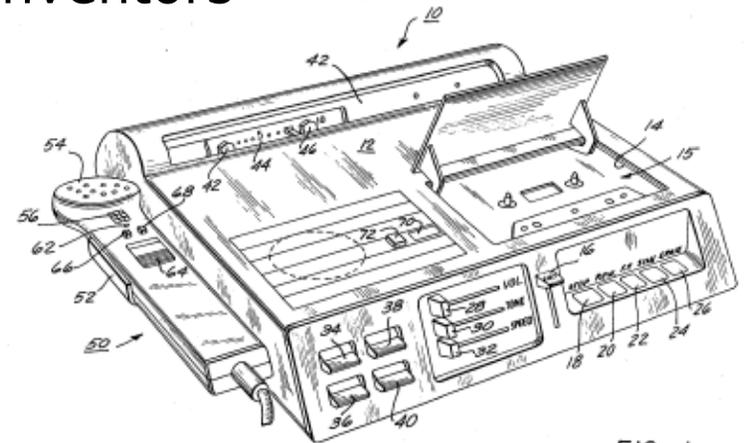
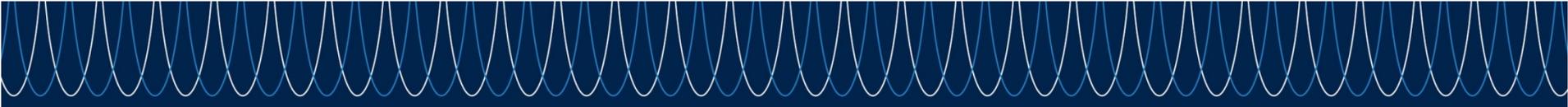


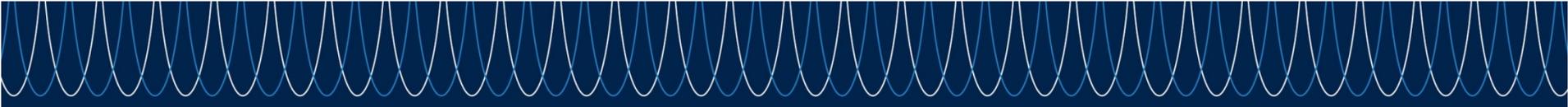
FIG. 1



# Enablement

The specification must be *enabling* as of the claimed priority date, and must teach those of *ordinary* skill how to make and use the *full scope* of the claimed invention *without undue experimentation*.

*Hybritech v. Monoclonal Antibodies*, 802 F.2d 1367 (Fed. Cir. 1986)



# Undue Experimentation – Multiple Factors to Consider

- ❖ Quantity of experimentation necessary
- ❖ Amount of direction or guidance presented
- ❖ 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
- ❖ Breadth of the claims

*In re Wands*, 858 F.2d 731 (Fed. Cir. 1988)

# Example of Reasonable Experimentation

## *Telectronics*

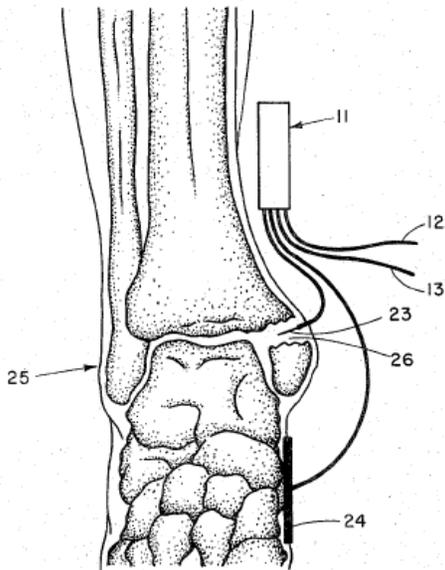


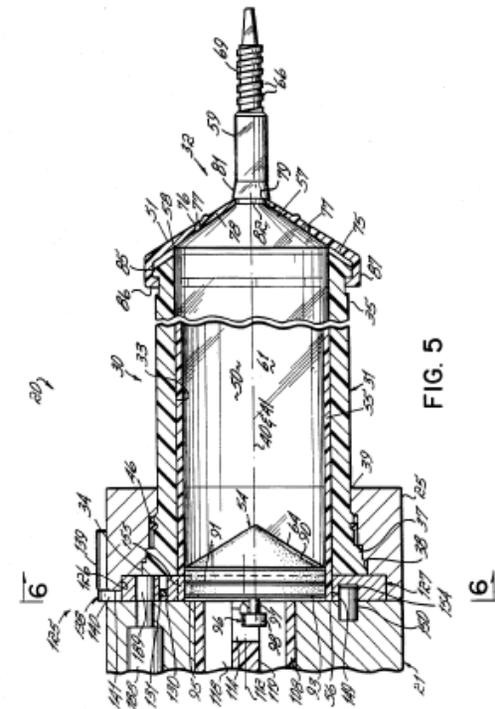
Fig. 3

- ❖ Claims to bone growth stimulator device enabled broad range of variations beyond disclosed embodiment that included stainless external anode.
- ❖ Infringer used electrical housing as titanium anode.
- ❖ Performing dose response tests to determine the level of current to use with other materials was not undue experimentation.

# Example of Undue Experimentation

## *Liebel-Flarsheim*

- ❖ Claims to patient fluid injector in continuing applications omitted pressure jacket limitation.
- ❖ Background described jacketless injectors as expensive and impractical.
- ❖ Inventors admitted pressure-jacketless system would have required more experimentation and testing.

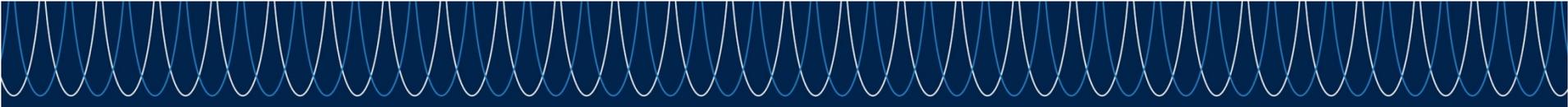


# Written Description and Enablement - Separate Tests?

- ❖ “The description requirement is ... separate from the enablement requirement ...” *In re Wilder* (1984)
- ❖ “The purpose of the [written] description requirement ... is to state what is needed to fulfill the enablement criteria.” *Kennecott* (1987)
- ❖ “The purpose of the 'written description' requirement is broader than to merely explain how to 'make and use'.” *Vas-Cath* (1991)
- ❖ Written description sufficiency is a matter of fact (*Union Oil* (2000)), while enablement is a matter of law (*BJ Services* (2003)).

## Written Description and Enablement - Separate Tests?

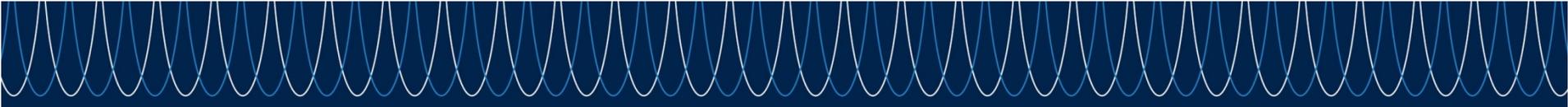
- ❖ Description of chemical and biotechnology inventions require “a precise definition, such as by structure, formula, chemical name, or physical properties, not a mere wish or plan for obtaining the claimed chemical invention.” *Eli Lilly* (1997)
- ❖ An enabling deposit of genetic material was insufficient/sufficient to support the written description requirement. *Enzo II* (2002)
- ❖ *Ariad Pharmaceuticals, Inc. v. Eli Lilly & Co.*, 560 F.3d 1366 (Fed. Cir. 2009) – hearing en banc



# Best Mode

- ❖ Determined by the knowledge of facts within the possession of the inventor at the time of filing.
- ❖ Designed to prevent a patentee from “holding back” knowledge from the public.
- ❖ **Active concealment or grossly inequitable conduct is not required to establish failure** to disclose the best mode.

*Robotic Vision Systems, Inc. v. View Engineering, Inc.*,  
112 F.3d 1163, 42 USPQ2d 1619 (Fed. Cir. 1997)



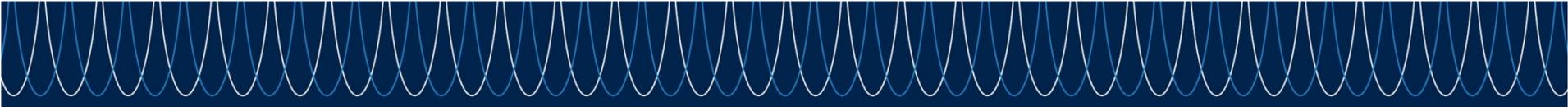
# Best Mode: Two-Step Test

## FR First Step (Subjective):

- Did the inventor(s) have a best mode of practicing the invention at the time of filing?

## FR Second Step (Objective):

- If there was a best mode, was it disclosed in sufficient detail to allow one skilled in the art to practice it?



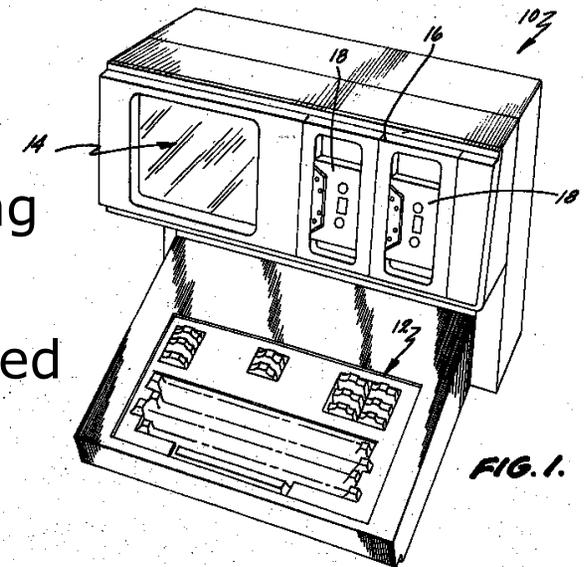
# Best Mode: Drafting Considerations

- ❖ Always determined with respect to claims
- ❖ Specific examples not required (but recommended)
- ❖ Designation not required (nor recommended)
- ❖ Updating not required when adding no matter
- ❖ Defects cannot be cured later

# Examples of Missing Best Mode

## *Northern Telecom*

- ❖ Claims were to computer data entry device.
- ❖ Only disclosed storage medium was standard audio cassette.
- ❖ At time of filing, Applicant was purchasing special tapes of its own design.
- ❖ Claims were invalid, even though disclosed audio tapes were enabling.



# Examples of Missing Best Mode

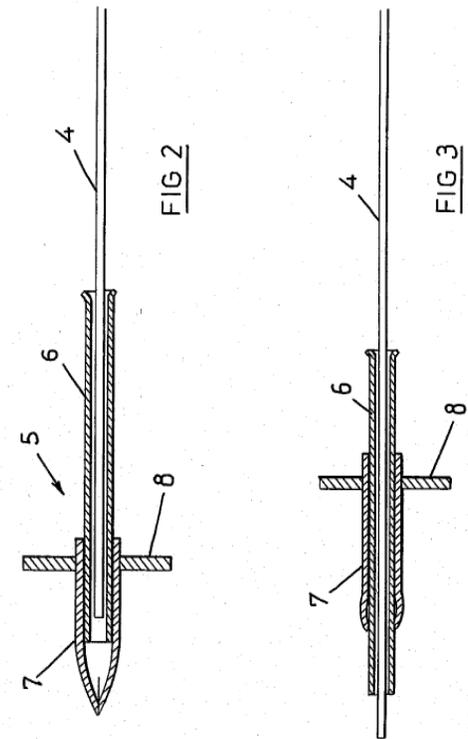
## *U.S. Gypsum*

- ❖ Patent concerned joint compounds to fill joints between gypsum wallboards.
- ❖ Original patent draft named an important ingredient by its third-party trade name; **management made attorney remove any reference to that name** in the final draft.
- ❖ Court found clear and convincing evidence that inventor considered this particular version part of his best mode.
- ❖ Claims were invalidated.

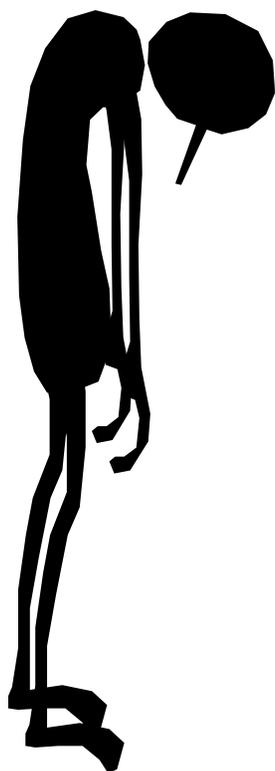
# Examples of Missing Best Mode

## *Go Medical*

- ❖ Patent to sheathed catheter issued from CIP.
- ❖ Prior application failed to disclose best mode, therefore priority claim invalid; claims anticipated by intervening prior art.
- ❖ Inventor admitted in deposition that at the time of filing the earlier application, making the sheath of a particular length was part of his “preferred embodiment.”
- ❖ As that length was not disclosed in the parent application, **summary judgment** granted.



# Examples of Adequate Best Mode

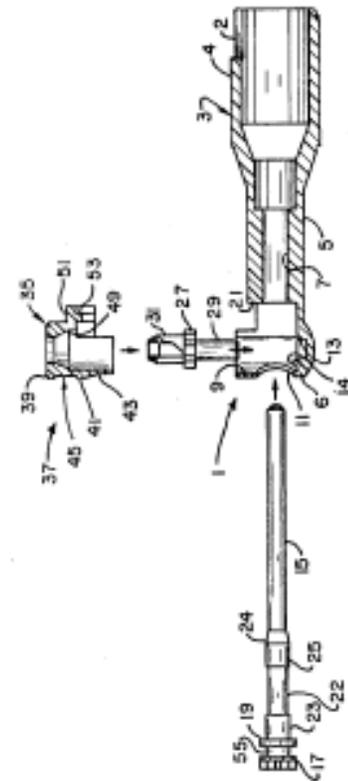


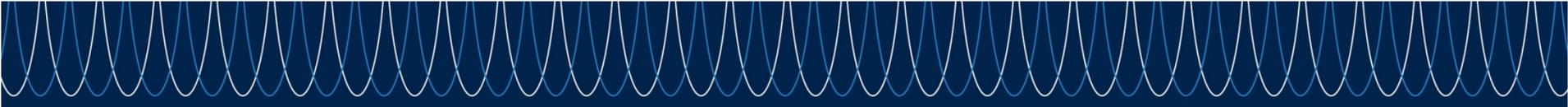
- ❖ *Eli Lilly v. Barr*
- ❖ Inventors did not disclose their:
  - Preferred method for making starting material
  - Preferred solvent for recrystallizing/purifying product
- ❖ But no best mode violation because:
  - Starting material/method not claimed; starting material commercially available
  - Recrystallization with a solvent disclosed but not claimed
  - Solvent selection routine to one of ordinary skill in the art

# Examples of Adequate Best Mode

## *Young Dental*

- ❖ FR Claims directed toward a tooth polishing device.
- ❖ FR Inventor did not disclose his:
  - Preferred gear ratio
  - Preferred grade of Lexan used for the body, and the grade of Celcon used for the gears
- ❖ FR But no best mode violation because:
  - Selection of gear ratio a routine design detail
  - Preferred grades of materials were common and their selection was readily apparent to one of ordinary skill





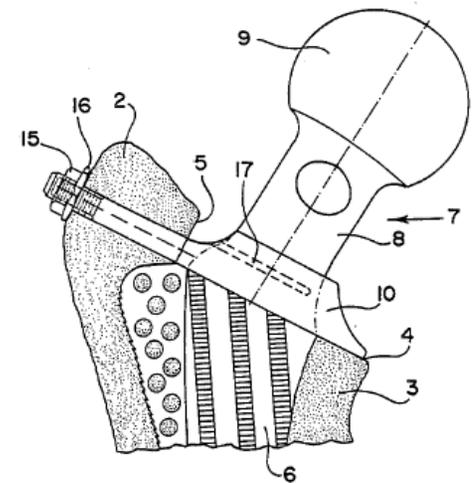
# Best Mode and Foreign Priority

- ❖ Priority application inventor(s) must have disclosed their best mode at time of filing, of the invention as ultimately claimed in the U.S. *Tyler Refrigeration* (1985)
- ❖ No need to update best mode disclosure when entering U.S., if not adding subject matter. *Transco Products* (1994)
- ❖ When adding subject matter, must disclose new refinements essential to the successful practice of the invention and related to the new matter. *Johns-Manville Corp.* (1983)

# Fixing §112 Problem by Filing CIP?

*Waldemar Link, GmbH*

- ❖ Original U.S. filing claimed DE priority.
- ❖ Examiner rejected claims under § 112 as lacking adequate written description, and objected to drawings as insufficient.
- ❖ Applicant filed new claims; received final rejection over prior art.
- ❖ Applicant filed CIP with improved drawings.
- ❖ Had final office action repeated the § 112 rejection, Applicant would have been estopped from claiming priority.

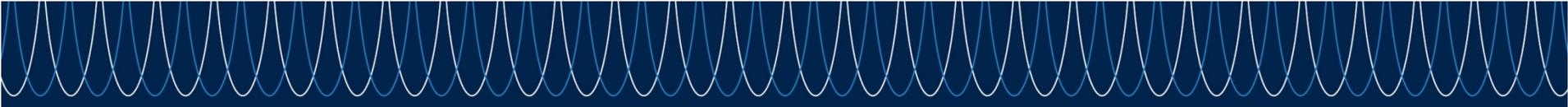


# PTO Drawing Requirement

- ❖ Whenever the nature of the subject matter sought to be patented admits of illustration by a drawing without its being necessary for the understanding of the subject matter and the applicant has not furnished such a drawing, the examiner will require its submission ... 37 CFR 1.81(c)

**NOTE: NEW MATTER TRAP**

- ❖ Drawings submitted after the filing date of the application may not be used to overcome any insufficiency of the specification ... 37 CFR 1.81(d)



# PTO Drawing Requirement

- ❖ **The drawing ... must show every feature of the invention specified in the claims.** However, conventional features disclosed in the description and claims, where their detailed illustration is not essential for a proper understanding of the invention, should be illustrated in the drawing in the form of a graphical drawing symbol or a labeled representation (e.g., a labeled rectangular box). 37 CFR 1.83(a)
- ❖ When the invention consists of an improvement on an old machine the drawing must when possible exhibit, in one or more views, the improved portion itself, disconnected from the old structure, and also in another view, so much only of the old structure as will suffice to show the connection of the invention therewith. 37 CFR 1.83(b)



# Thank You

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